Kentucky Law Journal

Volume 106 | Issue 1 Article 7

2017

Implementing Medicaid Health Homes to Provide Medication Assisted Treatment to Opioid Dependent Medicaid Beneficiaries

Page M. Smith
University of Kentucky College of Law

NOTES

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Page M. Smith[1]

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[1] M.P.H. Rollins School of Public Health, Emory University; J.D. Candidate 2018, University of Kentucky College of Law. My thanks to Professor Nicole Huberfeld and Dr. Victoria Phillips for their encouragement and feedback throughout the writing process. Special thanks to my husband, Corbin Smith, for his constant support and boundless patience.

INTRODUCTION

In 2011, prescription painkiller overdoses reached epidemic levels,[1] with three out of every four overdoses attributable to opioid pain relievers.[2] In the past fifteen years, deaths from prescription opioid overdoses in the United States have quadrupled, paralleling a quadruple increase in the rate opioids have been prescribed for chronic pain management.[3] Unfortunately, when the use of opioids expanded in the 1990s, it was not anticipated that the therapeutic benefits of opioids would quickly be outweighed by their addictiveness, resulting in not only "addiction, overdose, and death," but also "increasing use and overdoses of heroin and illicitly produced fentanyl."[4] Today, opioids have produced the "worst drug overdose epidemic in [US] history,"[5] creating an ongoing and "urgent need for a multifaceted, collaborative public health and law enforcement approach to the opioid epidemic . . . . "[6]

The exponential rise in the rate of fatal opioid overdoses largely stemmed from the unanticipated consequences of increased use of opioid prescriptions to treat chronic pain.[7] Beginning in the 1990s, several factors contributed to the significant

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[1] *Prescription Painkiller Overdoses at Epidemic Levels*, CDC (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html [https://perma.cc/QHW3-FLT2].

[2] NAT'L CTR. FOR INJURY PREVENTION & CONTROL, CDC, *Policy Impact: Prescription Painkiller Overdoses* (Nov. 2011), https://www.cdc.gov/drugoverdose/pdf/policyimpact-prescriptionpainkillerod-a.pdf [https://perma.cc/VKY5-FY3G]. Opioids include prescription opioids, fentanyl, and heroin, and are used to reduce pain. *Opioid Basics*, CDC, https://www.cdc.gov/drugoverdose/opioids/index.html [https://perma.cc/XX59-667M] (last updated Aug. 24, 2017). Common types of prescription opioids include "oxycodone (Oxycontin), hydrocodone (Vicodin), morphine, and methadone." *Id.* Fentanyl is a powerful "synthetic opioid pain reliever" used to treat severe pain. *Id.* "Heroin is an illicit opioid synthesized from morphine." Rose A. Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015*, CDC, 65 MORBIDITY & MORTALITY WKLY. REP. 1445, 1445 n.* (Dec. 30, 2016), https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm [https://perma.cc/M93C-U52X].

[3] Thomas R. Frieden & Debra Houry, *Reducing the Risks of Relief — The CDC Opioid-Prescribing Guideline*, 374 NEW ENG. J. MED. 1501, 1501 (2016).

[4] *Id.*

[5] Andrew Kolodny et al., *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, 36 ANN. REV. PUB. HEALTH 559, 560 (2015) (quoting Leonard J. Paulozzi, Medical Epidemiologist, Nat'l Ctr. for Injury Prevention & Control, Grand Rounds Presentation at Maimonides Medical Center Department of Psychiatry, Brooklyn, N.Y.: Promising Legal Responses to the Epidemic of Prescription Drug Overdoses in the U.S. (Dec. 2, 2010)); *see also* Frieden & Houry, *supra* note 3, at 1503 (stating that "no other medication routinely used for a nonfatal condition . . . kills patients" as frequently as opioids).

[6] Rudd et al., *supra* note 2, at 1446.

[7] *See Prescribing Data*, CDC, https://www.cdc.gov/drugoverdose/data/prescribing.html [https://perma.cc/QNZ9-LP8R] (last updated Aug. 30, 2017) (reporting that sales of prescription opioids quadrupled from 1999–2014, despite no changes in the amount of pain Americans report). Prescription opioids can either be immediate-release (IR) or extended release/long acting formulations (ER/LA), but risk of overdose and death is significantly higher with "ER/LA formulations." OFFICE OF THE ASSISTANT SEC'Y FOR PLANNING & EVALUATION, U.S. DEP'T OF HEALTH & HUMAN SERVS., OPIOID ABUSE IN THE U.S. AND HHS ACTIONS TO ADDRESS OPIOID-DRUG RELATED OVERDOSES AND DEATHS, 2 (Mar. 26, 2015), https://aspe.hhs.gov/system/files/pdf/107956/ib_OpioidInitiative.pdf [https://perma.cc/PRN5-CLGW] [hereinafter ASPE ISSUE BRIEF ON OPIOID ABUSE 2015] (citing CTR. FOR DRUG EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., FINAL RISK EVALUATION AND MITIGATION STRATEGY (REMS) REVIEW 6 (July 22, 2014),

rise in opioid prescribing, including: (1) an enhanced physician focus on the inadequacy of chronic pain treatment, (2) "new pain management standards from the Joint Commission on the Accreditation of Healthcare Organizations," which eventually lead to pain's recognition as a "fifth vital sign";[8] and, (3) aggressive and misleading marketing practices by pharmaceutical companies.[9] Unfortunately, widespread opioid prescriptions preceded the development of research-based prescribing guidelines that accounted for the efficacy, "safety, and economic efficiency of long-term opioid therapy."[10] Although some professional organizations, states, and federal agencies have devised clinical guidelines for opioid prescribing, the Centers for Disease Control and Prevention (CDC) published the first evidence-based, uniform prescribing guidelines in March 2016.[11] Ultimately, the lack of consensus on appropriate prescribing resulted in over-prescription and erratic prescription rates across states that cannot be explained by underlying variations in a state's health status.[12]

Thus, as opioid overdose deaths continue to rise across the U.S.,[13] prevention, treatment, and development of an effective response to opioid abuse have become pressing public health initiatives for state and federal governments.[14] In 2015, the

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https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/205777Orig1s000RiskR.pdf [https://perma.cc/QZ2H-Z7BB]).

[8] Kathryn F. Hawk et al., *Reducing Fatal Opioid Overdose: Prevention, Treatment and Harm Reduction Strategies*, 88 YALE J. BIOLOGY & MED. 235, 236 (2015) (citations omitted), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4553643/pdf/yjbm_88_3_235.pdf [https://perma.cc/8Z2F-G5K4]; *see also* Gary Franklin et al., *A Comprehensive Approach to Address the Prescription Opioid Epidemic in Washington State: Milestones and Lessons Learned*, 105 AM. J. PUB. HEALTH, 463, 464 (2015) (discussing "[t]he development of pain as the 'fifth vital sign.'" *But see* David W. Baker, *Joint Commission Statement on Pain Management*, JOINT COMMISSION (Apr. 18, 2016) (denying that the 2001 Joint Commission standards formally recognized pain as a vital sign).

[9] Frieden & Houry, *supra* note 3, at 1501; Hawk et al., *supra* note 8, at 236.

[10] Frieden & Houry, *supra* note 3, at 1501; Hawk et al., *supra* note 8, at 236.

[11] Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016*, CDC, 65 MORBIDITY & MORTALITY WKLY. REP. 1, 1–3 (Mar. 18, 2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm [https://perma.cc/L9XE-8EGH]. The CDC's guidelines were based on an intensive systematic review of scientific evidence and the input of experts and practitioners, federal agencies, professional and advocacy organizations, patient and provider groups, a federal advisory committee, peer reviewers, and public comments. *Id.* at 4–8; Frieden & Houry, *supra* note 3, at 1503.

[12] Dowell et al., *supra* note 11, at 1 (citing Leonard J. Paulozzi et al., *Vital Signs: Variation Among States in Prescribing of Opioid Pain Relievers and Benzodiazepines – United States, 2012*, CDC, 63 MORBIDITY & MORTALITY WKLY. REP. 563 (July 4, 2014), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6326a2.htm [https://perma.cc/6E7A-TSUX]).

[13] Rudd et al., *supra* note 2, at 1445. From 2014 to 2015 alone, drug overdoses involving an opioid increased approximately 15%. *Id.* at 1446 (calculating the percent change between 33,091 deaths involving an opioid in 2015 and 28,647 involving an opioid in 2014). But, the "rapid increase in deaths appears to be driven by heroin and synthetic opioids other than methadone" rather than prescription opioids (natural/semisynthetic opioids). *Id.*

[14] U.S. DEP'T OF HEALTH & HUMAN SERVS., *THE OPIOID EPIDEMIC: BY THE NUMBERS* 1, https://www.hhs.gov/sites/default/files/Factsheet-opioids-061516.pdf [https://perma.cc/TSY2-XY66]

U.S. Department of Health and Human Services (HHS) announced its commitment to decrease opioid overdoses, the prevalence of opioid use disorder,[15] and overall overdose mortality.[16] To achieve these goals, the Secretary's initiative focused on (1) opioid prescribing practices, (2) use and distribution of naloxone,[17] and (3) access to Medication Assisted Treatment (MAT),[18] areas targeting several of the interconnected dimensions of the opioid epidemic. This Note will examine access to MAT, analyzing the efficacy of an innovative care model that several states have implemented in their Medicaid programs to deliver MAT to opioid dependent beneficiaries.

Prior to enactment of the Patient Protection and Affordable Care Act (ACA),[19] Medicaid's role in financing substance abuse treatment was limited.[20] But, three provisions of the ACA, in combination with the Mental Health Parity and Addiction Equity Act of 2008 ("Equity Act"),[21] are expected to transform Medicaid into the largest payer of addiction treatment.[22] First, by offering states

(last updated June 2016) [hereinafter HHS OPIOID EPIDEMIC: BY THE NUMBERS]; *see also* ASPE ISSUE BRIEF ON OPIOID ABUSE 2015, *supra* note 7, at 1 ("addressing the opioid abuse problem" is a "high priority" for HHS).

[15] Opioid use disorder is also referred to as "opioid abuse or dependence" or "opioid addiction." *Opioid Basics*, supra note 2. This Note will use those terms interchangeably.

[16] ASPE ISSUE BRIEF ON OPIOID ABUSE 2015, *supra* note 7, at 1.

[17] Naloxone is a drug that reverses both prescription opioid and heroin overdoses. ASPE ISSUE BRIEF ON OPIOID ABUSE *Id.* at 5.

[18] *Id.* at 1. Medication Assisted Treatment (MAT) involves the use of three FDA-approved medications for treating opioid use disorders, including methadone, buprenorphine, or naltrexone, "in combination with counseling and behavioral therapies, to provide a whole-patient approach to the treatment of substance use disorders, including opioid use disorders." ASPE ISSUE BRIEF ON OPIOID ABUSE 2015, *supra* note 7, at 6; *see also* CMCS Informational Bulletin from Dirs. and Adm'rs of Various Pub. Health-Related Fed. Agencies on Medication Assisted Treatment for Substance Use Disorders 1, 3–4 (July 11, 2014), https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/CIB-07-11-2014.pdf [https://perma.cc/64HC-JXSD].

[19] Patient Protection and Affordable Care Act, Pub. L. No. 111–148, 124 Stat. 119 (2010) (codified in scattered sections of 42 U.S.C.).

[20] Christina Andrews et al., *Lessons from Medicaid's Divergent Paths on Mental Health and Addiction Services*, 34 HEALTH AFF. 1131, 1132–33 (2015); *see also* Jeffrey A. Buck, *The Looming Expansion and Transformation of Public Substance Abuse Treatment Under the Affordable Care Act*, 30 HEALTH AFF. 1402, 1402–03, 1408 (2011) (discussing the ACA's potential to integrate substance abuse treatment system into "mainstream of general health care"). Andrews et al. use addiction treatment synonymously with substance abuse treatment. *See* Andrews et al, *supra*.

[21] Emergency Economic Stabilization Act of 2008, Pub. L. No. 110–343, § 512, 112 Stat. 3765, 3881–93.

[22] Andrews et al., *supra* note 20, at 1131–33; *see also* KIRSTEN BERONIO ET AL., U.S. DEP'T OF HEALTH & HUMAN SERVS., AFFORDABLE CARE ACT WILL EXPAND MENTAL HEALTH AND SUBSTANCE USE DISORDER BENEFITS AND PARITY PROTECTIONS FOR 62 MILLION AMERICANS, 1, 3–4 (Feb. 2013), https://aspe.hhs.gov/system/files/pdf/76591/rb_mental.pdf [https://perma.cc/WWK3-ZZDX] (estimating that 62.5 million Americans (both Medicaid and non-Medicaid beneficiaries) will gain access to mental health and substance abuse benefits through the ACA and federal parity protections). *But see* Christina Andrews et al., *Despite Resources from the ACA, Most States Do Little to Help Addiction Treatment Programs Implement Health Care Reform*, 34 HEALTH AFF. 828, 834 (2015) (stating the ACA "has great potential to improve access to addiction treatment," but that the "implementation poses great challenges to the addiction treatment system"); Michael C. Barnes & Stacey L. Worthy, *Achieving Real Parity: Increasing Access to Treatment for Substance Use Disorders Under the Patient Protection and Affordable Care Act and the Mental Health and Addiction*

the ability to expand Medicaid to those under age 65 earning up to 133% of the Federal Poverty Level (FPL),[23] the ACA allows expansion states to greatly increase the number of beneficiaries eligible to receive substance abuse benefits.[24] Second, the ACA designates mental health and substance use disorder services as Essential Health Benefits (EHBs),[25] signifying that all insurance plans in the individual and small group markets, [26] as well as Medicaid Alternative Benefit Plans,[27] must cover such services.[28] Finally, the ACA makes the requirements of the Equity Act applicable to individual, small group,[29] and Alternative Benefit Plans,[30] thereby preventing the imposition of "financial requirements and treatment limitations" on substance abuse and mental health services that are "more restrictive than those

Equity Act, 36 U. ARK. LITTLE ROCK L. REV. 555, 557 (2014) (arguing that "prejudices" and "misunderstandings" about substance use disorders continue to thwart increased access to treatment despite passage of the ACA and the Mental Health Parity and Addiction Equity Act of 2008). At time of publication of this Note, Congress's "repeal-and-replace effort[s]" have failed three times in 2017, Rachel Roubein, *Timeline: The GOP's Failed Effort to Repeal ObamaCare*, HILL (Sept. 26, 2017, 8:02 PM), http://thehill.com/policy/healthcare/other/352587-timeline-the-gop-effort-to-repeal-and-replace-obamacare [https://perma.cc/ZGW4-SRA9], "demonstrat[ing] the difficulty in amending, let alone repealing, an imperfect law that over seven years has extended health insurance coverage to many Americans." KATHRYN S. BEARD & PAUL T. CLARK, DELAY, DEREGULATE, DERAIL – HEALTH CARE ROILED BY ACTIONS OF TRUMP AND CONGRESS 13 WOLTERS KLUWER (July 14, 2017). While the ACA's future remains uncertain, it is clear "federal spending on Medicaid and the opioid epidemic" will remain key points of contention in any future proposed health care bills. *See* Robert Pear & Jennifer Steinhauer, *G.O.P. Rift over Medicaid and Opioids Imperils Senate Health Bill*, N.Y. TIMES (June 20, 2017), https://www.nytimes.com/2017/06/20/us/politics/health-care-medicaid-opioid.html [https://perma.cc/KQ7L-3RWP].

[23] *See* Patient Protection and Affordable Care Act, Pub. L. No. 111–148, § 2001(a)(5), 124 Stat. 119, 274 (2010) (codified as amended at 42 U.S.C. § 1396a(*l*)(2)(C) (2012)). Under *NFIB v. Sebelius*, 132 S. Ct. 2566, 2607–08 (2012), states were given the option to expand Medicaid.

[24] *See* Andrews et al., *supra* note 22, at 828 (estimating that if all states expanded Medicaid, approximately five million uninsured Americans suffering from substance abuse could be eligible to receive insurance through Medicaid or insurance exchanges).

[25] *See* 42 U.S.C. § 18022 (2012 & Supp. III 2012). EHBs include the following categories of services: (1) ambulatory patient services, (2) emergency services, (3) hospitalization, (4) maternity and newborn care, (5) mental health and substance use disorder services, including behavioral health treatment, (6) prescription drugs, (7) rehabilitative and habilitative services and devices, (8) laboratory services, (9) preventive and wellness services and chronic disease management, and (10) pediatric services. *Id.* § 18022(b)(1) (2012). Within each of these categories, the Secretary of HHS is responsible for ensuring that the scope of benefits offered is "equal to the scope of benefits provided under a typical employer plan" and adequately accounts for the health care needs of a diverse patient population. *Id.* § 18022(b)(2)(A), (b)(4).

[26] 45 C.F.R. § 147.150(a) (2017).

[27] Alternative Benefit Plans cover most adults in the expansion population and are equivalent to what was previously described as benchmark coverage, or a plan satisfying the minimum Medicaid requirements. 42 U.S.C. § 1396u-7(a)(1)(A), (b) (2012); Julia Paradise, *Medicaid Moving Forward*, KAISER FAMILY FOUND. 4–5 (Mar. 9, 2015), http://kff.org/health-reform/issue-brief/medicaid-moving-forward/ [https://perma.cc/HX2Z-P48E].

[28] 42 C.F.R. § 440.335(b) (2017).

[29] 45 C.F.R. §§ 146.136, 147.160(a) (2017).

[30] 42 U.S.C. § 1396u-7(b)(6).

placed on medical and surgical benefits."[31] Consequently, as states attempt to address the rampant opioid epidemic, their Medicaid programs will play an important function, especially in funding prevention and treatment.[32]

In addition to Medicaid's enhanced financing role, Medicaid beneficiaries are disproportionately affected by the opioid epidemic.[33] Individuals with opioid dependency constitute a small portion of the total Medicaid population,[34] but in comparison to the general population, Medicaid recipients are more likely to be prescribed opioids,[35] die from opioid overdoses,[36] experience heroin abuse or dependence,[37] and suffer from comorbid conditions that diminish the efficacy of treatment.[38] Furthermore, because states dedicate a large percentage of their budgets to fund Medicaid,[39] and a minority of enrollees generate the majority of

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[31] Buck, *supra* note 20, at 1403. The Equity Act applies to group health plans, including Medicaid managed care. *Id.* But, the Equity Act is limited in its application because it does not mandate coverage of mental health and substance abuse. Barnes & Worthy, *supra* note 22, at 567. Rather, it only requires equivalent coverage for plans choosing to cover mental health and substance abuse. *Id.* (citing 29 U.S.C. § 1185a(b) (2012)).

[32] *See* Deborah Bachrach et al., *Medicaid: States' Most Powerful Tool to Combat the Opioid Crisis*, STATE HEALTH REFORM ASSISTANCE NETWORK 4 (July 2016), http://statenetwork.org/wp-content/uploads/2016/07/State-Network-Manatt-Medicaid-States-Most-Powerful-Tool-to-Combat-the-Opioid-Crisis-July-2016.pdf [https://perma.cc/B8M9-LSSB] ("Medicaid is the most powerful vehicle available to states to fund coverage of prevention and treatment for residents at risk for or actively battling opioid addiction.").

[33] CMCS Informational Bulletin from Vikki Wachino, Dir., Ctr. for Medicaid & CHIP Servs., on Best Practices for Addressing Prescription Opioid Overdoses, Misuse, & Addiction 2 (Jan. 28, 2016), https://www.medicaid.gov/federal-policy-guidance/downloads/CIB-02-02-16.pdf [https://perma.cc/785T-NJJU] [hereinafter CMS Best Practices for Addressing Prescription Opioid Overdoses, Misuse, & Addiction].

[34] Kathy Moses & Julie Klebonis, *Designing Medicaid Health Homes for Individuals with Opioid Dependency: Considerations for States*, CTRS. FOR MEDICARE & MEDICAID SERVS. 1 (Jan. 2015), https://www.medicaid.gov/state-resource-center/medicaid-state-technical-assistance/health-homes-technical-assistance/downloads/health-homes-for-opiod-dependency.pdf [https://perma.cc/5389-VZYG].

[35] CMS Best Practices for Addressing Prescription Opioid Overdoses, Misuse, & Addiction, *supra* note 33, at 2.

[36] Tami L. Mark et al., *Medicaid Coverage of Medications to Treat Alcohol and Opioid Dependence*, 55 J. SUBSTANCE ABUSE TREATMENT 1, 1 (2015), (citing Bridget M. Kuehn, *Payers Probe Ways to Help Curb Risky Prescribing*, 311 JAMA 1097, 1098 (2014)).

[37] *New Research Reveals the Trends and Risk Factors Behind America's Growing Heroin Epidemic*, CDC, (July 7, 2015, 1:00 PM), https://www.cdc.gov/media/releases/2015/p0707-heroin-epidemic.html [https://perma.cc/75B2-7GM7].

[38] Robin E. Clark et al., *Risk Factors for Relapse and Higher Costs Among Medicaid Members with Opioid Dependence or Abuse: Opioid Agonists, Comorbidities, and Treatment History*, 57 J. SUBSTANCE ABUSE TREATMENT 75, 75, 77 (2015); *see also* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-15-449, BEHAVIORAL HEALTH: OPTIONS FOR LOW-INCOME ADULTS TO RECEIVE TREATMENT IN SELECTED STATES 1–2, 6–7 (June 2015), http://www.gao.gov/assets/680/670894.pdf [https://perma.cc/GL6V-HV9D] [hereinafter GAO: BEHAVIORAL HEALTH] (highlighting the increased prevalence of behavioral conditions among Medicaid patients and the benefits of appropriate treatment).

[39] *See* Robin Rudowitz, *Medicaid Financing: The Basics*, KAISER FAMILY FOUND. 8–9 (Dec. 22, 2016), http://kff.org/medicaid/issue-brief/medicaid-financing-the-basics/ [https://perma.cc/NE2L-ZN4S].

spending,[40] states are constantly seeking cost-effective solutions to manage the complex health care needs of their Medicaid populations.[41]

A provision in the ACA encourages states to establish health homes, which combine physical and behavioral health[42] and long-term services, to provide higher quality and more individualized care to Medicaid beneficiaries with chronic conditions.[43] As of May 2017, twenty-one states and the District of Columbia are operating Medicaid health homes, but only three of those states, Maryland, Rhode Island, and Vermont, have designed health homes specifically to target those with opioid dependency.[44]

Although Medicaid expansion may have the most dramatic impact on a state's capacity to provide treatment for opioid dependency,[45] this Note will consider how

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[40] *See id.* at 4–5 (stating that elderly and disabled persons make up one-quarter of Medicaid enrollees, but account for almost two-thirds of Medicaid spending); KAISER COMM'N ON MEDICAID & THE UNINSURED, *Medicaid Health Homes for Beneficiaries with Chronic Conditions*, KAISER FAMILY FOUND. 4 (Aug. 2012), https://kaiserfamilyfoundation.files.wordpress.com/2013/01/8340.pdf [https://perma.cc/9CBR-BMAQ] [hereinafter KAISER, *Medicaid Health Homes*] ("[O]ver half of all Medicaid spending is attributable to the 5% of Medicaid beneficiaries with the highest costs.").

[41] *See* KAISER, *Medicaid Health Homes*, *supra* note 40, at 4 (noting that almost half of disabled Medicaid beneficiaries suffer from mental illness and nearly half have three or more chronic conditions). Major chronic conditions are prevalent among all Medicaid beneficiaries, with "more than 1 in 10" diagnosed with diabetes. *Id.*

[42] Services treating mental health and substance abuse conditions are considered behavioral health treatments. *See* GAO: BEHAVIORAL HEALTH, *supra* note 38, at 6–7.

[43] *See* 42 U.S.C. § 1396w-4 (2012); CTRS. FOR MEDICARE & MEDICAID SERVS., *Medicaid Health Homes: An Overview* 1 (May 2015), https://www.medicaid.gov/state-resource-center/medicaid-state-technical-assistance/health-homes-technical-assistance/downloads/medicaid-health-homes-overview.pdf [https://perma.cc/TS9G-5P3L] [hereinafter CMS, *Health Home Overview*]; *Health Homes*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/ltss/health-homes/index.html [https://perma.cc/67V7-AQ8R] (last visited Nov. 2, 2017). Under § 1396w-4(h)(B)(2), substance use disorder is considered a chronic condition.

[44] *See* CTRS. FOR MEDICARE & MEDICAID SERVS., *Medicaid Health Homes: SPA Overview* (May 2017), https://www.medicaid.gov/state-resource-center/medicaid-state-technical-assistance/health-homes-technical-assistance/downloads/hh-spa-overview.pdf [https://perma.cc/A6XK-93LP] [hereinafter CMS, *Medicaid Health Homes: SPA Overview*]; *see also* CTRS. FOR MEDICARE & MEDICAID SERVS., *Approved Medicaid Health Home State Plan Amendments*, https://www.medicaid.gov/state-resource-center/medicaid-state-technical-assistance/health-homes-technical-assistance/downloads/hh-map.pdf [https://perma.cc/Y6EV-2YSJ] (last updated May 2017). Each state implemented its Medicaid health home in 2013, Moses & Klebonis, *supra* note 34, at 3, but since that time Maryland appears to have broadened the focus of its health home from opioid use disorder to substance abuse disorder generally. *Compare* CTRS. FOR MEDICARE & MEDICAID SERVS., *State-by-State Health Home State Plan Amendment Matrix* 3, https://www.medicaid.gov/state-resource-center/medicaid-state-technical-assistance/health-homes-technical-assistance/downloads/hh-spa-at-a-glance-jul-2016.pdf [https://perma.cc/WJC6-YZ2V] (last updated July 2016) (showing that Maryland's target health home population included persons with opioid substance use disorder), *with* CMS, *Medicaid Health Homes: SPA Overview*, *supra*, at 2 (providing that Maryland's home health model focuses on substance use disorder treatment generally).

[45] *See generally* JUDITH DEY ET AL., BENEFITS OF MEDICAID EXPANSION FOR BEHAVIORAL HEALTH, U.S. DEP'T OF HEALTH & HUMAN SERVICES (Mar. 28, 2016), https://aspe.hhs.gov/sites/default/files/pdf/190506/BHMedicaidExpansion.pdf [https://perma.cc/BTP3-LSXN] (discussing expansion states' enhanced ability to care for beneficiaries with mental illness or

the health home model, regardless of a state's expansion status and present uncertainty surrounding the ACA's future,[46] offers all states an innovative approach to restructuring their Medicaid programs to better serve the complex needs of opioid dependent beneficiaries.[47] Specifically, this Note will examine the features of Vermont's Medicaid health home, assessing the benefits and challenges of Vermont's system and the feasibility of implementing the model in other states to deliver MAT to Medicaid recipients. Facing rising rates of prescription opioid abuse and dependence and heroin use, increasing health care expenditures on opioid dependent beneficiaries, and a failing treatment system, Vermont adopted its Hub and Spoke health home model to improve access to and the quality of MAT for its Medicaid beneficiaries.[48] But, unlike Maryland and Rhode Island,[49] in organizing its health home, Vermont integrated the two existing, but historically distinct providers of MAT, opioid treatment programs and buprenorphine prescribing physicians, to enhance care coordination, treatment capacity, and the provision of individualized care.[50]

Part I will explore the evolution of opioid epidemic and the adverse health outcomes that have resulted from increased opioid consumption, especially among Medicaid beneficiaries. Part II will discuss the solutions that are being proposed to curb opioid misuse, overdose, and addiction, focusing particularly on the provision of MAT and the issues plaguing access to substance abuse treatment in the U.S. Part III will examine the implementation and characteristics of Medicaid health

substance use disorder); *see also* Deborah Bachrach et al., *supra* note 32, at 1 (stating that "Medicaid is a far more powerful weapon" against the opioid epidemic in states that expanded Medicaid).

[46] *See* Peter D. Friedmann et al., *How ACA Repeal Would Worsen the Opioid Epidemic*, 376 NEW ENG. J. MED. e16(1), e16(2) (2017), http://www.nejm.org/doi/pdf/10.1056/NEJMp1700834 [https://perma.cc/JPD9-XUDD] (noting that with Donald Trump's profession to repeal the ACA, the "future of the ACA is precarious at best"). *But see supra* note 22 (evidencing that repeal and replace efforts have failed three times since the time Friedmann et al. was published). Nonetheless, President Trump has "vowed . . . that Republican efforts to repeal and replace the Affordable Care Act are not finished," Phil Mattingly, *Trump Vows GOP Will Continue Efforts to Repeal Obamacare*, CNN (Sept. 27, 2017, 2:56 PM), http://www.cnn.com/2017/09/27/politics/donald-trump-health-care-republicans/index.html [https://perma.cc/EA3N-GLJR], evidenced by his October 12, 2017, executive order eliminating "subsidies to health insurance companies that help pay out-of-pocket costs of low-income people . . . ." Robert Pear et al., *Trump to Scrap Critical Health Care Subsidies, Hitting Obamacare Again*, N.Y. TIMES (Oct. 12, 2017) https://www.nytimes.com/2017/10/12/us/politics/trump-obamacare-executive-order-health-insurance.html [https://perma.cc/PXA5-VCXA].

[47] *See* Buck, *supra* note 20, at 1404 (noting that ACA provisions other than Medicaid expansion have the opportunity to "affect the financing and character of public substance abuse treatment services").

[48] ASS'N OF STATE & TERRITORIAL HEALTH OFFICIALS & DE BEAUMONT FOUND., VERMONT CASE STUDY: MEDICATION ASSISTED TREATMENT PROGRAM FOR OPIOID ADDICTION 10, 13 (May 2014), http://www.astho.org/Health-Systems-Transformation/Medicaid-and-Public-Health-Partnerships/Case-Studies/Vermont-MAT-Program-for-Opioid-Addiction/ [https://perma.cc/C8F8-45WY].

[49] *See* Moses & Klebonis, *supra* note 34 (comparing the features of each state's medical home).

[50] Karen L. Casper & Anthony Folland, *Essential Elements of Vermont's "Hub and Spoke" Health Homes Model*, *in* MODELS OF INTEGRATED PATIENT CARE THROUGH OTPS AND DATA 2000 PRACTICES (Am. Ass'n for the Treatment of Opioid Dependence) 6–7, 10–11 (Feb. 22, 2016), http://www.aatod.org/policies/mat-hub-setting-whitepapers/ [https://perma.cc/JXF7-LEXU] (follow "Whitepaper #1" hyperlink).

homes, concentrating on the features of Vermont's system, including the impact it has had on MAT delivery and its ability to address the traditional shortcomings in the delivery of MAT. Finally, Part IV will consider the efficacy of Vermont's system, its limitations and its generalizability to other states seeking solutions to address opioid morbidity and mortality.

I. EVOLUTION OF THE OPIOID EPIDEMIC

A. Effect of the Exponential Increase in the Rate of Opioid Prescription

Despite debates surrounding the effect increased consumption and prescription of opioids has had on the prevalence of nonmedical opioid use,[51] or use of opioids without a prescription or in a manner other than as prescribed,[52] evidence shows the morbidity and mortality associated with nonmedical use is intensifying.[53] Over the last decade, emergency department visits and drug overdose deaths involving prescription opioids have increased exponentially;[54] and, the prevalence of opioid use disorder, or "problematic pattern[s] of opioid use leading to clinically significant impairment,"[55] among nonmedical users has risen nearly 125%.[56]

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[51] *Compare* Beth Han et al., *Nonmedical Prescription Opioid Use and Use Disorders Among Adults Aged 18 Through 64 Years in the United States, 2003–2013*, 314 JAMA 1468, 1471–72 (2015), http://jamanetwork.com/journals/jama/fullarticle/2456166 [https://perma.cc/HEF3-K4XX] (follow "Download PDF" hyperlink) (finding that "the percentage of nonmedical use of prescription opioids decreased" from 2003–2013), *and* Christopher M. Jones, *The Paradox of Decreasing Nonmedical Opioid Analgesic Use and Increasing Abuse or Dependence – An Assessment of Demographic and Substance Use Trends, United States, 2003–2014*, 65 ADDICTIVE BEHAVIORS 229, 231, 233 (2016) (finding a decline in nonmedical opioid use between 2003–2005 and 2012–2014), *with* Tulshi D. Saha et al., *Nonmedical Prescription Opioid Use and DSM-5 Nonmedical Prescription Opioid Use Disorder in the United States*, 77 J. CLINICAL PSYCHIATRY 772, 776 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5555044/pdf/nihms882236.pdf [https://perma.cc/YH22-M9XB] (finding that the prevalence of 12-month and lifetime nonmedical opioid use increased from 1.8% and 4.7%, respectively, in 2001–2002 to 4.1% and 11.3% in 2012–2013).

[52] Kolodny et al., *supra* note 5, at 563. Nonmedical opioid use is also considered use of opioids for the experience or feeling they cause, *id.* at 563, or use of illicit opioids. Hawk et al., *supra* note 8, at 236.

[53] *See* Han et al., *supra* note 51, at 1472–74, 1477 (noting that despite the decrease in the percentage of nonmedical use, the "morbidity and mortality associated with nonmedical use of prescription opioids" has increased); Jones, *supra* note 51, at 231–33 (noting that the "encouraging" decreasing trends in nonmedical use are "tempered by the significant increases in rates of . . . opioid . . . abuse or dependence"); Saha et al., *supra* note 51, at 776 (finding that the increased prevalence of nonmedical opioid use produced a corresponding increase in "[nonmedical prescription opioid use]-associated morbidity and mortality."

[54] Han et al., *supra* note 51, at 1469.

[55] AGENCY FOR HEALTHCARE RESEARCH & QUALITY, U.S. DEP'T OF HEALTH & HUMAN SERVICES, *Medication-Assisted Treatment Models of Care for Opioid Use Disorder* 1 (Feb. 24, 2016), https://ahrq-ehc-application.s3.amazonaws.com/media/pdf/opioid-use-disorder_research-protocol.pdf [https://perma.cc/7YR9-44WN] (quoting *Opioid Use Disorder Diagnostic Criteria*, *Substance-Related and Addictive Disorders*, *in* AM. PSYCHIATRIC ASS'N, DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS 1 (5th ed. 2013), http://pcssmat.org/wp-content/uploads/2014/02/5B-DSM-5-Opioid-Use-Disorder-Diagnostic-Criteria.pdf [https://perma.cc/MHE5-NDDK]). Opioid use

Statistics may show that rates of nonmedical use have remained relatively stable, but the frequency and intensity of prescription opioid use among nonmedical users has increased significantly, resulting in a corresponding rise in the rates of opioid abuse or dependence.[57] In addition to problems with opioid dependence, the misuse of prescription opioids is also closely connected to the rise in the use of illicit opioids, including heroin and illicitly manufactured fentanyl.[58] The addictive nature of prescription opioids makes nonmedical use "a significant risk factor for heroin use,"[59] with "four in five new heroin users start[ing] out by misusing prescription opioids."[60] Moreover, while the majority of nonmedical users obtain medications from a friend or relative, frequent nonmedical users, those with the highest use and therefore the highest risk of overdose, most often obtain opioids from physician prescriptions.[61]

But, regardless of whether a person uses opioids medically as prescribed or nonmedically,[62] merely initiating treatment with opioids enhances the risk of opioid use disorder, overdose, and addiction.[63] A recent study found that 1 in 550 patients "receiving opioids for chronic noncancer pain . . . died from opioid-related overdose

disorder also "involves misuse or abuse of prescription opioids or illicit heroin." *Id.* Characteristics of opioid use disorder include: "unsuccessful efforts to cut down or control use" and use resulting in social problems and "a failure to fulfill major role obligations at work, school, or home." *Opioid Use Disorder Diagnostic Criteria*, *supra*, at 1.

[56] Saha et al., *supra* note 51, at 772–73, 776.

[57] Han et al., *supra* note 51, at 1472; Jones, *supra* note 51, at 230, 233.

[58] Rudd et al., *supra* note 2, at 1450; Frieden & Houry, *supra* note 3, at 1501.

[59] Rudd et al., *supra* note 2, at 1450.

[60] HHS OPIOID EPIDEMIC: BY THE NUMBERS, *supra* note 14, at 2; *see Opioids*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., https://www.samhsa.gov/atod/opioids [https://perma.cc/8G22-YJW8] (last updated Feb. 23, 2016) (describing how repeated use of opioids increases one's tolerance, which may ultimately lead a person to turn to the black market for prescription drugs and illicit opioids).

[61] Christopher M. Jones et al., Research, Letter, *Sources of Prescription Opioid Pain Relievers by Frequency of Past-Year Nonmedical Use: United States, 2008–2011*, 174 JAMA INTERNAL MED. 802, 802–03 (2014), http://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1840031 (follow "Download PDF" hyperlink) [https://perma.cc/C8QP-MJH4]. The majority of nonmedical users reported 1 to 199 days of nonmedical use, while the highest risk group reported 200 to 365 days of nonmedical use. *Id.* Those in the highest risk group were also more likely to receive drugs from drug dealers. *Id.*

[62] Medical opioid users are those taking opioid pain relievers as prescribed. Hawk et al., *supra* note 8, at 236. But, "[t]he pathophysiology and acute medical management of an opioid overdose [are] similar irrespective of whether the opioid that was taken was legally prescribed or illegally bought . . . ." *Id.* at 237. Even "strict adherence to instructions" does not protect a person from "fatal overdose." *Id.* at 236.

[63] Dowell et al., *supra* note 11, at 2; Frieden & Houry, *supra* note 3, at 1501. Opioid use disorder is often referred to as "abuse or dependence" and "is different from tolerance (diminished response to a drug with repeated use) and physical dependence (adaptation to a drug that produces symptoms of withdrawal when the drug is stopped)." Dowell et al., *supra* note 11, at 2. Overdose is "[i]njury to the body" that occurs "when a drug is taken in excessive amounts." *Opioid Basics*, *supra* note 2. The injury caused by an overdose can be fatal or nonfatal. *Id.* Addiction is "continued use of a drug despite negative consequences." Kolodny et al., *supra* note 5, at 560.

at a median of 2.6 years" from the date of first prescription,[64] demonstrating that a history of being prescribed opioid pain medications increases the likelihood of adverse health outcomes.[65] Consequently, repeated exposure to opioids places both individuals using opioids for pain relief and nonmedical users at higher risk of developing addiction.[66]

Ultimately, the exponential increase in the prescription and use of opioids underlies both "distinct but interconnected trends" defining the current opioid epidemic: (1) a 15-year increase in prescription opioid overdose deaths and (2) a rise in illicit opioid overdoses.[67]

B. The Opioid Crisis Within the Medicaid Population

Although opioid prescribing has increased dramatically among both privately and publicly insured populations,[68] the detrimental effects of overprescribing are particularly concerning for the Medicaid population. At the outset, one's status as a Medicaid beneficiary increases the odds of suffering from opioid abuse or dependence.[69] The Medicaid population disproportionately suffers from the following risk factors, shown to make one more susceptible to prescription opioid abuse: (1) "overlapping prescriptions from multiple providers and pharmacies;"[70] (2)

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[64] Dowell et al., *supra* note 11, at 2 (citing Eric Kaplovitch et al., *Sex Differences in Dose Escalation and Overdose Death During Chronic Opioid Therapy: A Population-Based Cohort Study*, PLOSONE, Aug. 20, 2015, at 1, 4–7). The rate of death was even more dramatic as opioid dosages increased, escalating to one in thirty-two for patients receiving more than 200 morphine milligram equivalents. *Id.*

[65] *Id.*

[66] Kolodny et al., *supra* note 5, at 560.

[67] *Opioid Data Analysis*, CDC, https://www.cdc.gov/drugoverdose/data/analysis.html [https://perma.cc/TU6U-QJKX] (last updated Feb. 9, 2017); *see also* Frieden & Houry, *supra* note 3, at 1501 (noting that the quadrupled rate of opioid prescribing in the past fifteen years is "tightly correlated" with the quadruple increase in deaths from prescription opioid overdose). From 1999–2015, the majority of drug overdoses involved an opioid, but the increase in the "opioid-involved death rate" from 2014–2015 seems to be attributable to heroin and illicitly manufactured fentanyl. Rudd et al., *supra* note 2, at 1445–46.

[68] Mark D. Sullivan et al., *Trends in Use of Opioids for Non-Cancer Pain Conditions 2000–2005 in Commercial and Medicaid Insurance Plans: The TROUP Study*, 138 PAIN 440, 447–48 (2008).

[69] *See* Han et al., *supra* note 51, at 1470 (finding that the prevalence of opioid use disorders was higher among Medicaid beneficiaries); Jones, *supra* note 51, at 233.

[70] *Prescription Opioids: Risk Factors*, CDC (footnotes omitted), https://www.cdc.gov/drugoverdose/opioids/prescribed.html [https://perma.cc/T3B8-43KB] (follow "Risk Factors" tab) (last updated Aug. 29, 2017); *see* Zhuo Yang et al., *Defining Risk of Prescription Opioid Overdose: Pharmacy Shopping and Overlapping Prescriptions Among Long-Term Opioid Users in Medicaid*, 16 J. PAIN 445, 449–50 (2015) (finding that among a population of 90,010 Medicaid beneficiaries using opioids long-term, 6.7% had both "pharmacy shopping behavior and overlapping prescriptions," making this population six times more likely to overdose than those with neither condition). Beneficiaries with overlapping prescriptions only were more likely to overdose than those with pharmacy shopping only. *Id.* at 450. Because there is no uniform definition of "pharmacy shopping," the study examined several combinations of time intervals (90 days, 180 days, and 1 year)

"high daily doses of prescription pain relievers;"[71] (3) "mental illness or a history of alcohol or other substance abuse;"[72] and, (4) "living in rural areas and having low income."[73] A study examining the prevalence of indicators of misuse and inappropriate opioid prescribing among Medicaid beneficiaries found that Medicaid patients were more likely than privately insured patients to be suffering from at least one or more adverse indicators at the time of their prescription.[74] In

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and the number of pharmacies visited during the time interval (≥3, ≥4, ≥5). *Id.* at 447. Yang et al. found that regardless of time interval, the percentage of patients with overdose events increased linearly as the number of pharmacies used increased. *Id.* at 448. "Overlapping prescriptions were defined as [two] prescriptions of the same drug type that overlapped by ≥25% of the days prescribed, with the initial dispensed prescription having a supply time of five days or longer." *Id.* at 447; *See also* Sullivan et al., *supra* note 68, at 442, 447 (comparing patterns of opioid use in a privately insured population and a Medicaid population and finding that the "rates of opioid use were markedly higher" among the Medicaid population). Specifically, Medicaid patients were more likely to be prescribed opioids and more likely to receive a longer total supply, a higher cumulative yearly dose, and a greater number of opioid prescriptions. *Id.* at 447.

[71] *Prescription Opioids: Risk Factors*, *supra* note 70 (footnotes omitted). High daily opioid dose is considered "a prescribed daily dose of 100 morphine milligram equivalents (MME) or greater." Karin A. Mack et al., *Prescription Practices Involving Opioid Analgesics Among Americans with Medicaid, 2010*, 26 J. HEALTH CARE FOR POOR & UNDERSERVED 182, 185 (2015); *see also id.* at 183–88 (analyzing 2010 prescription claims data and finding seventeen percent of a study population of 359,368 Medicaid beneficiaries were prescribed high daily doses of opioids "at least once during the study period," and of those beneficiaries, "[seventeen percent] had [high] daily doses . . . for more than 90 days"); Yang et al., *supra* note 70, at 449 (finding that twenty-eight percent of Medicaid beneficiaries with overlapping prescriptions and twenty-four percent of those with pharmacy shopping and overlapping prescriptions were prescribed high daily doses). Sullivan et al. found that "cumulative opioid dose per day supplied was similar" between Medicaid and privately insured populations, but that Medicaid beneficiaries received "more prescriptions and higher opioid doses per prescription." Sullivan et al., *supra* note 68, at 445–46.

[72] *Prescription Opioids: Risk Factors*, *supra* note 70 (footnotes omitted); *see* GAO: BEHAVIORAL HEALTH, *supra* note 38, at 1–2 (stating that in comparison to privately insured persons, Medicaid beneficiaries have "a higher rate of behavioral health conditions," which include mental health and substance use conditions).

[73] *Prescription Opioids: Risk Factors*, *supra* note 70 (footnotes omitted). Living in a rural area and having low income are interconnected. *See* Vann R. Newkirk II & Anthony Damico, *The Affordable Care Act and Insurance Coverage in Rural Areas*, KAISER COMM'N ON MEDICAID & THE UNINSURED 1 (May 2014), https://kaiserfamilyfoundation.files.wordpress.com/2014/05/8597-the-affordable-care-act-and-insurance-coverage-in-rural-areas1.pdf [https://perma.cc/KJ2E-9FSS] (stating that approximately sixteen percent of the U.S. population lives in rural areas and that rural areas have higher shares of "low-to-moderate income individuals"). Persons with incomes below 138% of the federal poverty level are considered low-income, which is also the income threshold to qualify for Medicaid in expansion states. GAO: BEHAVIORAL HEALTH, *supra* note 38, at 4. Approximately 25% of those living in rural areas have incomes below the FPL. *See* Newkirk & Damico, *supra*, at 1.

[74] Mack et al., *supra* note 70, at 183, 195. In this study, indicators of "potential misuse or inappropriate prescription practices," included: (1) "opioid overlap," or opioid prescriptions overlapping seven or more days; (2) "opioid and benzodiazepine overlap," or prescriptions of opioids and benzodiazepine overlapping seven or more days; (3) "high daily opioid dose"; and, (4) "rapid opioid dose escalation," or "having a 50% or greater increase in mean MMEs per month twice consecutively during the year." *Id.* at 185. In addition to "increased numbers of opioid prescriptions," each of the indicators measured has been associated with "increased risk of clinically recognized abuse." *Id.* at 195 (footnotes omitted). In Mack et al., approximately 40% of the study population of Medicaid beneficiaries had at least one indicator of potential inappropriate use or prescribing. *Id.* at 188.

addition to demographic characteristics that make the Medicaid population more vulnerable to opioid use disorder, "inappropriate prescribing practices and opioid prescribing rates are [also] substantially higher among Medicaid patients."[75]

The underlying risk factors associated with one's Medicaid status also make Medicaid beneficiaries more susceptible to nonmedical use of opioids and the corresponding adverse consequences of such use. Compared to privately insured opioid users, users in the Medicaid population have a higher prevalence of opioid use disorders and a higher frequency of nonmedical use, placing them at greater risk of being high-intensity opioid users.[76] Not surprisingly, Medicaid beneficiaries are also most susceptible to developing heroin abuse or dependence.[77] But, in addition to risks of high-intensity use, the Medicaid population disproportionately suffers from complex physical and mental health conditions,[78] such as other drug or alcohol disorders or mental health illnesses, which are strongly associated with nonmedical opioid use and opioid use disorder.[79]

Thus, the adverse health outcomes stemming from the increasing use of opioids can only partially be explained by harmful prescribing practices and the addictive characteristics of opioids. Efforts to curb opioid use disorder among the Medicaid population require strategies that account for the complex interaction between the baseline risks of initiating treatment with opioids and the socioeconomic factors predisposing Medicaid beneficiaries to worse health outcomes.

II. ADDRESSING OPIOID MISUSE, OVERDOSE, AND ADDICTION THROUGH MEDICATION ASSISTED TREATMENT

A. Proposed Solutions for Addressing Opioid-Related Morbidity and Mortality

Because worsening health outcomes associated with opioid consumption have predominantly been attributed to the exponential growth in prescribing rates, efforts to alleviate the harmful effects of opioid misuse have focused on controlling the prescription and supply of opioids. For instance, almost all states have implemented prescription drug monitoring programs (PDMPs), state-based

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[75] *Prescription Opioids: Risk Factors*, *supra* note 70.

[76] Han et al., *supra* note 51, at 1470, 1472, 1476.

[77] *New Research Reveals the Trends and Risk Factors Behind America's Growing Heroin Epidemic*, *supra* note 37.

[78] *See* KAISER COMM'N ON MEDICAID & THE UNINSURED, *Medicaid: A Primer*, 1, 3, 10, 21 (Mar. 2013), http://kaiserfamilyfoundation.files.wordpress.com/2010/06/7334-05.pdf [https://perma.cc/QWZ7-AAFV] (providing an overview of the complex health care needs of Medicaid beneficiaries).

[79] *See* Jones, *supra* note 51, at 233–34 ("[P]eople with opioid analgesic abuse or dependence are using other substances in high-risk ways . . . with [greater than one in three] having past-year alcohol abuse or dependence and nearly [one] in [five] having past-year marijuana or prescription sedative or tranquilizer abuse or dependence."); *id.* at 234 (citations omitted) (using multiple substances is a "risk factor for overdose death"); Saha et al., *supra* note 51, at 775 (noting that nonmedical use of opioids and opioid disorder were "strongly related" to other mental health and substance disorders).

electronic databases that track the dispensation of prescription drugs and store individual patient data to identify patients at risk of inappropriate use or overdose.[80] Similarly, several states and professional organizations have developed prescribing guidelines to educate providers on the risk of prescribing opioids, provide appropriate dosing thresholds, and recommend strategies to identify and minimize patient misuse.[81] But, solutions targeting only supply side issues neglect patient characteristics that drive one's demand for opioids. [82]

While primary prevention strategies[83] may reduce opioid use and abuse among persons who have not previously used opioids or diminish access to those at higher risk of overdose, such strategies are inadequate for dealing with the large number of persons already dependent on prescription opioids or heroin.[84] An effective public health response to the opioid epidemic must combine primary, secondary, and tertiary prevention strategies to: (1) prevent development of new cases of opioid use disorder; (2) identify high-risk patients and treat opioid-addicted patients before serious complications arise; and, (3) provide effective addiction treatment to those already suffering from opioid use disorder.[85]

Although states seem to be actively pursuing interventions addressing opioid prescribing, they are largely failing at expanding access to MAT, with one report finding that merely three states had adequate capacity to provide MAT to residents with opioid dependence.[86] Not surprisingly, there is a significant discrepancy between the number of patients needing treatment and a state's capacity to deliver treatment, leaving over 1.5 million of the 2.5 million Americans suffering from opioid abuse or dependence without treatment.[87] The dire need for substance abuse

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[80] ASPE ISSUE BRIEF ON OPIOID ABUSE 2015, *supra* note 7, at 4; Deborah Dowell et al., *Mandatory Provider Review and Pain Clinic Laws Reduce the Amounts of Opioids Prescribed and Overdose Death Rates*, 35 HEALTH AFF. 1876, 1876 (2016).

[81] *See* Dowell et al., *supra* note 11, at 2–3.

[82] Wilson M. Compton et al., *Prescription Opioid Abuse: Problems and Responses*, 80 PREVENTIVE MED. 5, 6 (2015).

[83] Primary prevention efforts are designed to decrease the incidence of a disease or condition. Kolodny et al., *supra* note 5, at 565.

[84] Dowell et al., *supra* note 80, at 1881–82.

[85] Kolodny et al., *supra* note 5, at 565–68. Secondary prevention "screen[s] for a health condition after its onset but before it causes serious complications." *Id.* at 567. Tertiary prevention "involve[s] both therapeutic and rehabilitative measures once a disease is firmly established." *Id.* at 568. In the context of opioid addiction, the goal of tertiary prevention is to "prevent overdose deaths, medical complications, psychosocial deterioration, transition to injection drug use, and injection-related infectious diseases." *Id.*

[86] *See* NAT'L SAFETY COUNCIL, PRESCRIPTION NATION 2016: ADDRESSING AMERICA'S DRUG EPIDEMIC 13–15, http://www.nsc.org/RxDrugOverdoseDocuments/Prescription-Nation-2016-American-Drug-Epidemic.pdf [https://perma.cc/TNS2-XTGC] (last visited Nov. 4, 2017) (examining the number of states that satisfied six indicators thought to be critical in effectively addressing opioid epidemic). A majority of states met indicators relating to prescription drug monitoring programs and prescription of naloxone, while the fewest number of states met requirements for availability of opioid use disorder treatment. *Id.*

[87] Christopher M. Jones et al., *National and State Treatment Need and Capacity for Opioid Agonist Medication-Assisted Treatment*, 105 AM. J. PUB. HEALTH e55, e57 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4504312/pdf/AJPH.2015.302664.pdf [https://perma.cc/F574-RSA8]; Nora D. Volkow et al., *Medication-Assisted Therapies — Tackling the Opioid-Overdose Epidemic*, 370 NEW ENG. J. MED. 2063, 2064 (2014),

treatment is further illustrated by the rapidly growing number of deaths involving heroin,[88] which opioid abusers often transition to because of its lower price and increased accessibility.[89] Therefore, truly impacting opioid-related morbidity and mortality requires acknowledgment of underlying substance use disorder and subsequently expanding access to treatment.

B. Overview of Medication Assisted Treatment

Opioids are highly addictive because of their ability to suppress feelings of pain and induce euphoria.[90] Repeated exposure to opioids produces structural and functional changes in the brain that result in dependence or subsequently addiction, which causes persons to experience severe withdrawal symptoms when they reduce or stop using the drug.[91] Treating opioid use disorder is difficult for several reasons, including "the relapsing nature of [the] condition, the frequent presence of psychiatric and medical comorbidities, and the disproportionate impact on those in socioeconomically disadvantaged settings with limited access to care."[92] The most effective substance abuse treatments provide a comprehensive set of services, including "medical, social, psychological, and rehabilitative" components designed to address the complex care needs of patients.[93]

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http://www.nejm.org/doi/pdf/10.1056/NEJMp1402780 [https://perma.cc/EY5H-QUZB]. Approximately 1.9 million of the 2.5 million are addicted to opioid painkillers. NAT'L SAFETY COUNCIL, *supra* note 86, at 8. Rates of opioid abuse and dependency far exceed maximum treatment capacity. *Id.* at 26.

[88] *See* Rudd et al., *supra* note 2, at 1445–46; *New Research Reveals the Trends and Risk Factors Behind America's Growing Heroin Epidemic*, *supra* note 37.

[89] Theodore J. Cicero et al., *The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years*, 71 JAMA PSYCHIATRY 821, 825 (2014), http://jamanetwork.com/journals/jamapsychiatry/fullarticle/1874575 [https://perma.cc/8LGN-WPFD] (follow "Download PDF" hyperlink). Dependence on prescription opioids is strongest risk factor for heroin abuse or dependence); *New Research Reveals the Trends and Risk Factors Behind America's Growing Heroin Epidemic*, *supra* note 37.

[90] Kolodny et al., *supra* note 5, at 560; *Misuse of Prescription Drugs*, *Opioids*, NAT'L INST. ON DRUG ABUSE, https://www.drugabuse.gov/publications/research-reports/misuse-prescription-drugs/which-classes-prescription-drugs-are-commonly-misused [https://perma.cc/FS99-7WP5] (last updated Aug. 2016).

[91] *Misuse of Prescription Drugs*, *Opioids*, *supra* note 90.Withdrawal symptoms include: "yawning and other sleep problems, sweating more than normal, anxiety or nervousness, muscle aches and pains, stomach pain, nausea, or vomiting, diarrhea, and weakness." U.S. DEP'T OF HEALTH & HUMAN SERVS. & SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., *Medication-Assisted Treatment for Opioid Addiction*: *Facts for Families & Friends* 1, 9 (2014) [https://perma.cc/N3BB-9WXP].

[92] ROGER CHOU ET AL., AGENCY FOR HEALTHCARE RESEARCH & QUALITY, TECHNICAL BRIEF NO. 28, PUB. NO. 16(17)-EHC039-EF, MEDICATION-ASSISTED TREATMENT MODELS OF CARE FOR OPIOID USE DISORDER IN PRIMARY CARE SETTINGS 1 (Dec. 2016) (footnotes omitted) https://ahrq-ehc-application.s3.amazonaws.com/media/pdf/opioid-use-disorder_technical-brief.pdf [https://perma.cc/W2B9-ZQY4].

[93] U.S. DEP'T OF HEALTH & HUMAN SERVS., *Addressing Prescription Drug Abuse in the United States: Current Activities and Future Opportunities* 31, https://www.cdc.gov/drugoverdose/pdf/hhs_prescription_drug_abuse_report_09.2013.pdf [https://perma.cc/T7LY-ZC47] (last visited Nov. 4, 2017).

MAT is a "whole-patient approach"[94] to substance abuse treatment that combines the use of three FDA-approved medications, methadone, buprenorphine, or naltrexone,[95] with behavioral therapies to "reestablish normal brain functioning, reduce cravings, and prevent relapse."[96] The medication component "block[s] the euphoric . . . effects of opioids, reduce[s] the craving for opioids, and . . . mitigate[s] the symptoms of withdrawal," facilitating the patient's ability to engage in behavioral therapies, which "address the psychosocial contributors to [opioid use disorder,] . . . improve retention in care[,]"[97] and promote positive lifestyle changes.[98] To be effective, MAT should be provided in a "clinically-driven, person-centered, and individualized setting,"[99] capable of managing patients' comorbid physical and mental conditions.[100] In fact, a study examining the efficacy of buprenorphine or methadone treatment among Medicaid patients diagnosed with opioid abuse or dependence found that inadequate management of patients' preexisting substance abuse and mental health conditions was associated with significantly higher treatment costs and rates of relapse.[101]

Thus, the benefit of MAT is dependent upon the ability to provide treatment that simultaneously addresses the totality of a patient's comorbid substance use disorders and mental health problems.[102] Unfortunately, societal misunderstanding regarding MAT and opioid dependence and the laws regulating the provision of MAT, has created a delivery system that is not only inadequate to satisfy current demand for treatment but also incapable of providing coordinated, comprehensive services adequate to meet patients' complex health care needs.[103]

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[94] CMS Best Practices for Addressing Prescription Opioid Overdoses, Misuse, & Addiction, *supra* note 33, at 13.

[95] The FDA has approved three medications for treating opioid use disorders: (1) methadone, (2) buprenorphine, and (3) naltrexone. CMCS Informational Bulletin from Dirs. and Adm'rs of Various Pub. Health-Related Fed. Agencies on Medication Assisted Treatment, *supra* note 18, at 3–4. The medication selected for treatment depends upon the severity of the patient's opioid use disorder, but generally each medication is used to reduce or eliminate the patient's withdrawal symptoms. *See* Kyle Kampman & Margaret Jarvis, *American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use*, 9 J. ADDICTION MED. 358, 361–63 (2015).

[96] CMCS Informational Bulletin from Dirs. and Adm'rs of Various Pub. Health-Related Fed. Agencies on Medication Assisted Treatment, *supra* note 18, at 2 (footnote omitted).

[97] CHOU ET AL., *supra* note 92, at 1–2; *see also* CMCS Informational Bulletin from Dirs. and Adm'rs of Various Pub. Health-Related Fed. Agencies on Medication Assisted Treatment, *supra* note 18, at 2 (footnote omitted) (discussing the use of medication to allow utilization of behavioral therapy).

[98] U.S. DEP'T OF HEALTH & HUMAN SERVS. & SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., *supra* note 91, at 4–5.

[99] CHOU ET AL., *supra* note 92, at 1 (footnote omitted).

[100] *See* CHOU ET AL., *supra* note 92, at 11; Clark et al., *supra* note 38, at 78.

[101] Clark et al., *supra* note 38, at 76–78.

[102] *See id.* at 77–78.

[103] *Id.* at 78; *see* KENNETH B. STOLLER ET AL., AM. ASS'N FOR THE TREATMENT OF OPIOID DEPENDENCE, INTEGRATED SERVICE DELIVERY MODELS FOR OPIOID TREATMENT PROGRAMS IN AN ERA OF INCREASING OPIOID ADDICTION, HEALTH REFORM, AND PARITY 1–2 (July 13, 2016), http://www.aatod.org/wp-content/uploads/2016/07/2nd-Whitepaper-.pdf [https://perma.cc/78MB-SJD9] (calling for integrated service delivery among opioid treatment programs, medical providers, and behavioral health providers).

C. Barriers to the Expansion of Medication Assisted Treatment

Despite evidence that MAT is an effective, safe, and cost-saving measure to help patients recover from opioid use disorder and reduce the risk of other health conditions associated with drug abuse, several barriers have limited access to and use of MAT.[104]

i. Stigmatization of Opioid Dependence and Medication Assisted Treatment

Deeply rooted societal misconceptions have led to the characterization of drug dependence and addiction as an individual's moral problem or willful choice rather than a medical condition.[105] In fact, there are no health conditions associated with more "social disapproval and discrimination" than drug dependence.[106] Personally faulting individuals with drug dependence rather than embracing addiction as a chronic medical disorder, such as asthma, diabetes, or hypertension,[107] has far reaching detrimental effects including: (1) serving as "a major obstacle to personal and family recovery, [(2)] contribut[ing] to the marginalization of addiction professionals[,] . . . and [(3)] limit[ing] the type and magnitude of . . . resources allocated to . . . drug-related problems."[108]

In addition to the social stigma directed toward addicted individuals, MAT itself is tainted by the perception that the medication component "merely replace[s] one addiction with another."[109] This misconception has produced skepticism among medical providers

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[104] Onur Baser et al., *Cost and Utilization Outcomes of Opioid-Dependence Treatments*, 17 AM. J. MANAGED CARE S235, S245–47 (2011), http://www.ajmc.com/journals/supplement/2011/a369_june11/a369_11jun_alcohol_s235to48/P-4 [https://perma.cc/R2WP-HH4F] (follow "PDF" hyperlink); Volkow et al., *supra* note 87, at 2064–65.

[105] Yngvild Olsen & Joshua M. Sharfstein, Opinion, *Confronting the Stigma of Opioid Use Disorder and Its Treatment*, 311 JAMA 1393, 1393 (2014), http://jamanetwork.com/journals/jama/article-abstract/1838170 [https://perma.cc/THS9-J5UU] (follow "Download PDF" hyperlink); WILLIAM L. WHITE, LONG-TERM STRATEGIES TO REDUCE THE STIGMA ATTACHED TO ADDICTION, TREATMENT, AND RECOVERY WITHIN THE CITY OF PHILADELPHIA 11–12 (2009), http://www.williamwhitepapers.com/pr/2009Stigma%26methadone.pdf [https://perma.cc/689B-HZDP]; *see also* Compton et al., *supra* note 82, at 6 ("Opioid use disorder is a neurobiological disorder that produces well defined changes to the reward circuitry within the brain and a severe withdrawal syndrome that can make it very difficult to recover."); WHITE, *supra*, at 9 (footnote omitted) ("Stigma is the experience of being 'deeply discredited' due to one's 'undesired differentness.' To be stigmatized is to be held in contempt, shunned, or rendered socially invisible because of a socially disapproved status.").

[106] WHITE, *supra* note 105, at 9–10 (footnote omitted).

[107] SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., HHS PUB. NO. 12-4214, MEDICATION-ASSISTED TREATMENT FOR OPIOID ADDICTION IN OPIOID TREATMENT PROGRAMS: A TREATMENT IMPROVEMENT PROTOCOL TIP 43, at 3 (2017), https://www.ncbi.nlm.nih.gov/books/NBK64164/pdf/Bookshelf_NBK64164.pdf [https://perma.cc/R8AL-5C4G].

[108] WHITE, *supra* note 105, at 2.

[109] Volkow et al., *supra* note 87, at 2065; JOHNS HOPKINS BLOOMBERG SCH. OF PUB. HEALTH, THE PRESCRIPTION OPIOID EPIDEMIC: AN EVIDENCE-BASED APPROACH 41 (Nov. 2015), https://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-

and a tendency for addiction treatment facilities to favor abstinence models,[110] which are less effective than MAT in "reducing the frequency and quantity of opioid use[,] . . . [diminishing] risk of overdose, [and] improving social functioning."[111] In fact, compared to "time-limited medication . . . or psychosocial and abstinence interventions,"[112] the combination of counseling and medication through MAT "is more effective at treatment retention and reduction of heroin and prescription opiate abuse."[113] Therefore, societal misunderstanding, among both the general population and health care providers, regarding the benefits of MAT seems to be a continuing obstacle in expanding access to MAT.

ii. Legal Framework Regulating the Provision of Medication Assisted Treatment

Outside of pervasive societal stigmatization, federal and state regulation of the medications used in MAT, specifically, methadone and buprenorphine, has also significantly affected the availability of MAT. Because methadone and buprenorphine are controlled substances,[114] they are subject to the Controlled Substances Act (CSA),[115] which imposes strict requirements when these medications are prescribed and used for opioid addiction treatment.[116]

Following passage of the CSA, physicians could prescribe methadone for opioid addiction for the first time but subject to significant limitations.[117] Under the CSA, methadone is considered a Schedule II drug[118] and therefore can only legally be

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effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf [https://perma.cc/9XGQ-TB5Y].

[110] Volkow et al, *supra* note 87, at 2065; *see also* CHOU ET AL., *supra* note 92, at 27 (highlighting the "pervasive" stigma toward MAT among "physicians, clinic staff, patients, law enforcement, policymakers, insurers, and the community").

[111] AGENCY FOR HEALTHCARE RESEARCH & QUALITY, *supra* note 55, at 1.

[112] Time limited medications are those used in detoxification or tapering. Mary Kate Mohlman et al., *Impact of Medication-Assisted Treatment for Opioid Addiction on Medicaid Expenditures and Health Services Utilization Rates in Vermont*, 67 J. SUBSTANCE ABUSE TREATMENT 9, 10 (2016) http://www.journalofsubstanceabusetreatment.com/article/S0740-5472(15)30065-9/pdf [https://perma.cc/9T8Q-ZFV5].

[113] *Id.*; *see also* CMCS Informational Bulletin from Dirs. and Adm'rs of Various Pub. Health-Related Fed. Agencies on Medication Assisted Treatment, *supra* note 18, at 5 ("Research shows that when treating SUDs, a combination of medication and behavioral therapies is the most effective.").

[114] A controlled substance is "a drug or other substance, or immediate precursor," included in schedules I, II, III, IV, or V of the Controlled Substances Act. 21 U.S.C. § 802(6) (2012).

[115] *See generally* 21 U.S.C. §§ 801–890, 901–904, 951–971 (2012).

[116] U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-16-833, OPIOID ADDICTION: LAWS, REGULATIONS, AND OTHER FACTORS CAN AFFECT MEDICATION-ASSISTED TREATMENT ACCESS 5–8, 7 n.8 (2016), http://www.gao.gov/assets/690/680264.pdf [https://perma.cc/XY9Z-Y5A5].

[117] *Id.* at 10–13 (discussing the significant limitations the CSA placed on physicians ability to prescribe methadone); Barnes & Worthy, *supra* note 22, at 564 (citing Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91–513, 84 Stat. 1236 (codified as amended at 21 U.S.C. §§ 801– 852 (2011))).

[118] Schedule II drugs have the "highest potential for abuse among scheduled drugs with an accepted medical use;"; abuse of Schedule II drugs may result in "severe psychological or physical dependence." U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-16-833, OPIOID ADDICTION: LAWS, REGULATIONS, AND OTHER FACTORS CAN AFFECT MEDICATION-ASSISTED TREATMENT ACCESS at 6–7 (2016).

administered or dispensed in an opioid treatment program (OTP),[119] a practitioner or facility certified by Substance Abuse and Mental Health Services Administration (SAMSHA) and registered by the Drug Enforcement Administration (DEA) to provide opioid treatment.[120] To receive SAMSHA certification, an OTP must meet federal opioid treatment standards, which specify the patients that are eligible to receive treatment and the services that must be provided, including: "medical, counseling, vocational, educational, and other assessment and treatment services."[121] In addition to restrictions on location, only practitioners who obtain separate OTP registration may administer or dispense methadone.[122] Not surprisingly, the highly regulated nature of methadone treatment has produced significant barriers to access, including "waiting lists for treatment entry, limited geographic coverage, limited insurance coverage, and the requirement that many patients receive methadone at the OTP daily."[123]

In contrast to methadone, buprenorphine is a Schedule III drug[124] and is subject to less stringent limitations. Although buprenorphine can also be prescribed in OTPs, the Drug Addiction Treatment Act of 2000 (DATA)[125] expanded access to buprenorphine by allowing qualified physicians to obtain waivers (DATA waivers) from the CSA to dispense or prescribe buprenorphine in an outpatient setting.[126] Among other requirements, obtaining a waiver requires a practitioner to have the capacity to directly provide or refer patients to appropriate counseling services.[127]

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[119] 42 C.F.R. § 8 (2017).

[120] U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-16-833, OPIOID ADDICTION: LAWS, REGULATIONS, AND OTHER FACTORS CAN AFFECT MEDICATION-ASSISTED TREATMENT ACCESS
10–12 (2016).

[121] 42 C.F.R. § 8.12 (2017); U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-16-833, OPIOID ADDICTION: LAWS, REGULATIONS, AND OTHER FACTORS CAN AFFECT MEDICATION-ASSISTED TREATMENT ACCESS 12 (2016).

[122] U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-16-833, OPIOID ADDICTION: LAWS, REGULATIONS, AND OTHER FACTORS CAN AFFECT MEDICATION-ASSISTED TREATMENT ACCESS 10 (2016).

[123] Jones et al., *supra* note 87, at e55 (footnotes omitted). As of July 2016, there were approximately "1,400 OTPs in the [U.S.], treating approximately 350,000 patients" daily. STOLLER ET AL., *supra* note 103, at 1. OTPs operate in all states except North Dakota and Wyoming. Jones et al., *supra* note 87, at e59–60.

[124] Schedule III drugs have an accepted medical use and less potential for abuse than drugs in Schedules I and II, but "abuse of [Schedule III] drug[s] may lead to moderate or low physical dependence or high psychological dependence." U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-16-833, OPIOID ADDICTION: LAWS, REGULATIONS, AND OTHER FACTORS CAN AFFECT MEDICATION-ASSISTED TREATMENT ACCESS 6 (2016).

[125] Children's Health Act of 2000, Pub. L. No. 106–310, § 3502, 114 Stat. 1101, 1222–27 (codified as amended at 21 U.S.C. § 823(g)).

[126] U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-16-833, OPIOID ADDICTION: LAWS, REGULATIONS, AND OTHER FACTORS CAN AFFECT MEDICATION-ASSISTED TREATMENT ACCESS 13 (2016); Jones et al., *supra* note 87, at e55.

[127] 21 U.S.C. § 823(g)(2)(B)(ii) (2012).

Originally, the DATA allowed physicians to prescribe buprenorphine to up to thirty patients,[128] but the law was later amended to allow physicians who had been prescribing for one year to submit a revised waiver to treat up to 100 patients.[129] Most recently, eligibility for DATA waivers was extended to qualifying nurse practitioners and physicians' assistants[130] and the patient capitation limit was raised to 275 patients for certain physicians; [131] both changes are expected to further enhance providers' ability to provide MAT with buprenorphine.[132] Yet, the drastic growth in treatment capacity through buprenorphine and DATA-waived physicians has not produced a parallel reduction in the rates of opioid abuse and dependence, which continued to steadily rise over the course of these regulatory changes.[133]

Though the effect of the most recent modifications remains to be seen, prior data illustrate that even the most recent modifications facilitating the prescription of buprenorphine may have a minimal impact on patient access to MAT. For instance, as of 2012, six years after the patient limit was increased to 100 patients, only 28% of DATA-waived physicians nationwide had patient limits of 100, and no state had more than 45% of DATA-waived physicians at the 100-patient limit.[134] Moreover, studies have found that an estimated 34% to 56% of physicians with waivers do not actually prescribe buprenorphine; and, of the physicians that do prescribe buprenorphine, the majority do not reach their patient limit.[135] The more lenient regulation of buprenorphine has also had a limited effect on OTPs.[136] The majority of OTPs continue to provide only methadone treatment,[137] despite the fact that OTPs are not subject to limitations on the number of patients who can receive buprenorphine prescriptions.[138]

Overall, the marginal impact of regulation enabling the prescription of buprenorphine is concerning for several reasons. First, it demonstrates that even a dramatic increase in treatment capacity may be insufficient to alleviate the

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[128] *Id.* § 823(g)(2)(B)(iii) (2000) (amended 2006).

[129] *Id.* § 823(g)(2)(B)(iii) (2012).

[130] Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114–198, § 303(a)(1), 130 Stat. 695, 720–22.

[131] 42 C.F.R. § 8.610 (2017).

[132] Charles Townley & Hannah Dorr, *Integrating Substance Use Disorder Treatment and Primary Care*, NAT'L ACAD. FOR STATE HEALTH POLICY 5–6 (Feb. 2017), http://nashp.org/wp-content/uploads/2017/02/Primary-Care-Integration-Brief.pdf [https://perma.cc/NB4Y-PY66]; *see also* 21 U.S.C. § 823(g)(2)(B)(iii) (2012) (giving SAMSHA the authority to increase patient limits).

[133] *See* Jones et al., *supra* note 87, at e57–e58. For an illustration of the changes in opioid abuse or dependence and treatment capacity, see Table 1 and Figure 1 on e57 and e58, respectively.

[134] *Id.* at e59, Table 2.

[135] *Id.* at e55.

[136] *Id.* at e60.

[137] *Id.* (citing SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., HHS PUB. NO. 14-4807, 2011 OPIOID TREATMENT PROGRAM SURVEY: DATA ON SUBSTANCE ABUSE TREATMENT FACILITIES WITH OTPS 71 (Aug. 2013), https://www.samhsa.gov/data/sites/default/files/OTP2011_Web/OTP2011_Web/OTP2011_Web.pdf [https://perma.cc/68VB-E5S9].

[138] Jones et al., *supra* note 87, at e60.

discrepancy between the need for and receipt of treatment for opioid use disorder.[139] Second, it indicates that reducing opioid-related morbidity and mortality cannot be achieved merely through expanding access to treatment, whether by raising patient capitation limits or allowing more types of providers to prescribe buprenorphine.

While stricter regulations may more harshly affect access to MAT with methadone, pervasive barriers, including "provider availability[,] . . . willingness to prescribe, . . . low provider confidence in addressing addiction, limited access to addiction experts, lack of institutional or office support, lack of behavioral health services, and reimbursement concerns,"[140] also plague access to buprenorphine. Thus, it seems that factors beyond stringent laws regulating the administration and prescription of medications used in MAT underlie the problems with patient access.

Although laws restricting the dispensation of methadone and buprenorphine have contributed to the gap between treatment need and capacity, strategies to improve the delivery of MAT exist within our current legal framework. Merely expanding treatment capacity will not overcome the cumulative effects of societal stigma and the laws regulating addiction treatment, which over time have severed substance abuse treatment from the mainstream health care system.[141] Because the efficacy of MAT, especially among Medicaid beneficiaries, is largely dependent upon management of a patient's comorbid conditions, improving delivery of MAT requires solutions that enhance not only access to and use of MAT, but also provide coordinated care through a variety of treatment services.

III. MEDICAID HEALTH HOMES AND THE PROVISION OF MEDICATION ASSISTED TREATMENT

A. Current State of Medicaid Coverage of Medication Assisted Treatment

Because of Medicaid beneficiaries' increased susceptibility to opioid use disorder and the Medicaid program's augmented role in financing substance abuse under the ACA, states have a significant interest in understanding how the provision of MAT will impact not only total health care expenditures, but also the health outcomes of their beneficiaries.[142] States' Medicaid policies vary widely on the coverage of and limits placed on MAT, but over the last decade there has been

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[139] *See id.* at e57 (noting that the "marked[]" increase in treatment capacity did not significantly close the "gap in treatment need and capacity").

[140] *Id.* at e55.

[141] *See* Buck, *supra* note 20, at 1402 (noting that "treatment of substance abuse disorders occurs predominantly in a separate specialty services sector"); Olson & Sharfstein, *supra* note 105, at 1393–94 (stating that one factor impeding expansion of MAT is "the separation of opioid use disorder treatment from the rest of health care").

[142] Mohlman et al., *supra* note 112, at 10.

a general shift toward policies favoring coverage of the medications involved in MAT.[143] Studies analyzing the availability of medications and the characteristics of benefit designs in states' Medicaid programs often cite the following elements as barriers to MAT access: (1) the preferred drug list,[144] (2) prior authorization,[145] (3) quantity and duration limits,[146] and (4) behavioral health requirements.[147] Regardless of the way a state organizes the delivery of MAT to its beneficiaries, the specific elements of each state's benefit design will undoubtedly affect cost, access, and use of MAT. While being mindful of these baseline variances in states' MAT coverage, this Note will focus more on the infrastructure of Vermont's delivery system and whether this framework, which integrates OTPs and buprenorphine prescribing physicians to provide two tiers of patient care,[148] will be a feasible model for other states.

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[143] Rachel M. Burns et al., *Policies Related to Opioid Agonist Therapy for Opioid Use Disorders: The Evolution of State Policies from 2004 to 2013*, 37 SUBSTANCE ABUSE 63, 65 (2015), http://www.tandfonline.com/doi/pdf/10.1080/08897077.2015.1080208?needAccess=true [https://perma.cc/YY3F-BSWS].

[144] A Medicaid agency's preferred drug list designates drugs as either preferred or non-preferred. CMCS Informational Bulletin from Dirs. and Adm'rs of Various Pub. Health-Related Fed. Agencies on Medication Assisted Treatment for Substance Abuse Disorders, *supra* note 18, at 7. Preferred drugs can be prescribed without prior authorization for payment coverage, while non-preferred drugs cannot. *Id.*; *see* Burns et al., *supra* note 143, at 65 (finding that not all states cover both methadone and buprenorphine); Mark et al., *supra* note 36, at 3 (urging states to reassess their preferred drug lists to cover more medications used to treat opioid addiction); SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., HHS PUB. NO. SMA-14-4854, MEDICAID COVERAGE AND FINANCING OF MEDICATIONS TO TREAT ALCOHOL AND OPIOID USE DISORDERS 17–18, 45–62 (2014), http://store.samhsa.gov/shin/content/SMA14-4854/SMA14-4854.pdf [https://perma.cc/7GYX-MX7H] (depicting availability of medications on each states' preferred drug list).

[145] Prior authorization signifies that a "prescriber must obtain permission from Medicaid or the agency's vendor." CMCS Informational Bulletin from Dirs. and Adm'rs of Various Pub. Health-Related Fed. Agencies on Medication Assisted Treatment for Substance Use Disorders, *supra* note 18, at 7; *see* Burns et al., *supra* note 143, at 66 (warning that prior authorization can be a barrier to both providers and patients); Mark et al., *supra* note 36, at 3 (noting that prior authorization can be helpful for ensuring lower cost medications are tried first, but cautioning that prior authorization can also "cause administrative burdens that reduce access to medications"); SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., *supra* note 144, at 28 (reiterating concerns about prior authorization).

[146] *See* Mark et al., *supra* note 36, at 3 (stating that durational or lifetime limits on addiction medications is inconsistent with the view that "[o]pioid addiction is considered a chronic disease" and generally inconsistent with medical evidence); *id.* at 4 (noting that limiting dosages may interfere with the efficacy of treatment).

[147] States may require documentation that beneficiaries receiving FDA-approved medications for addiction treatment have either been referred or have started receiving behavioral therapy along with their medication. CMCS Informational Bulletin from Dirs. and Adm'rs of Various Pub. Health-Related Fed. Agencies on Medication Assisted Treatment, *supra* note 18, at 7; *see* Burns et al., *supra* note 143, at 66 (noting that counseling requirements may improve adherence to treatment, but also may deter initiation and continuance of treatment).

[148] Casper & Folland, *supra* note 50, at 5, 17–19.

B. Features of a Medicaid Health Home

Over time, laws regulating the dispensation of MAT medications have produced a fragmented delivery system for MAT, segregating substance abuse treatment from the overall health care system and creating explicit divisions among OTPs and other MAT providers.[149] Not only has the current infrastructure for MAT proven inadequate to meet the demands of the growing number of opioid dependent patients, it is also not equipped to treat the complex health needs of those seeking MAT. This is significant for several reasons. First, from a population health standpoint, the growing number of persons suffering from opioid dependence is producing a parallel shift in the prevalence of heroin use and dependence.[150] Second, from a cost perspective, expanding access to MAT is an extremely costly endeavor.[151] Although it is likely that a state would be able to offset direct medication costs through a reduction in spending on other health care costs, such as inpatient and outpatient care,[152] states have a strong incentive to implement MAT programs that successfully treat patients while conserving costs. The existing arrangement for providing MAT is not sustainable. But, by building integration and care coordination into the current delivery system, the Medicaid health home seems to offer a potential solution to the provision of MAT.

The Medicaid health home is a care delivery model derived from the patient centered medical home (PCMH), an approach characterized by a dynamic patient-physician relationship whereby the patient's primary care physician directs, coordinates, and monitors the patient's care across various medical disciplines and community-based services.[153] Under the ACA, states have the option to create health homes through state plan amendments to provide medical care for three categories of beneficiaries: (1) persons suffering from at least two chronic conditions, (2) persons with one chronic condition and at risk of developing another, and (3) persons with "[one] serious and persistent mental health condition."[154] The "designated provider" of a patient's care, or the central component of the health home, may be a single physician, a practice group, an

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[149] *Id.* at 6; STOLLER ET AL., *supra* note 103, at 1.

[150] Richard C. Dart et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 NEW ENG. J. MED. 241, 247 (2015), http://www.nejm.org/doi/pdf/10.1056/NEJMsa1406143 [https://perma.cc/YM5E-M7YW]; Jones, *supra* note 51, at 233–34.

[151] *See* Baser et al., *supra* note 104, at S240, S243, S245–46 (comparing health care costs and utilization among patients receiving opioid-dependence treatment with or without medication and finding that total medication costs were significantly greater for those receiving medication); Mohlman et al., *supra* note 112, at 10 (noting that MAT is associated with significantly higher costs than "tapering, abstinence, or psychosocial interventions").

[152] Baser et al., *supra* note 104, at S245–46; Mohlman et al., *supra* note 112, at 10.

[153] Amanda Cassidy, *Patient-Centered Medical Homes*, 29 HEALTH AFF., Sept. 14, 2010, at 1–2, http://www.healthaffairs.org/do/10.1377/hpb20100914.118477/full/healthpolicybrief_25.pdf [https://perma.cc/VF8S-PDBP]; KAISER, *Medicaid Health Homes*, *supra* note 40, at 4–5.

[154] 42 U.S.C. § 1396w-4(a), (h) (2012).

entity, such as a community health center, or a "team of health care professionals," including physicians, nurses, nutritionists, social workers, and other professionals.[155] Regardless of provider type, health homes must provide six core services to eligible beneficiaries: "[1] comprehensive care management; [2] care coordination . . . ; [3] comprehensive transitional care . . . ; [4] patient and family support . . . ; [5] referral to community and social support services . . .; and [6] use of health information technology to link services . . . ."[156] Ultimately, by devising individualized health care plans that "coordinate[] and integrate[] all clinical and non-clinical services and supports" necessary to meet the patient's needs,[157] health homes seek to improve health care outcomes and reduce the costs of caring for clinically complex patients.

Most states exercising the Medicaid health home option have targeted chronic conditions and serious mental illness, but Vermont, Maryland, and Rhode Island created health homes specifically targeting beneficiaries with opioid dependence.[158] In all three states, OTPs serve as designated providers, operating as a central contact and referral point for patients.[159] But, Vermont's Hub and Spoke model is unique in that it integrates OTPs with buprenorphine prescribing health care providers to provide patients with two levels of care and ensure patients receive care appropriately tailored to the complexity of the patient's addictions and other health conditions.[160] Because opioid dependent Medicaid beneficiaries are likely to suffer from or develop comorbid physical and mental health conditions,[161] the health home's intricate coordination of "physical and behavioral health services" seems to offer an ideal mechanism through which MAT can be delivered.[162]

C. Vermont's Response to the Opioid Drug Crisis and Features of Vermont's Medicaid Health Home

Over the last two decades, Vermont, has experienced an exponential rise in opioid-related morbidity and mortality,[163] including most recently, a nearly 40% rise in heroin dependency.[164] In 2012, despite consistent rankings as the "healthiest state" on various health measures, Vermont ranked 34th for the highest prevalence

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[155] See *id.* § 1396w-4(a), (h)(5)–(7), for the types of providers and facilities that are considered health homes.

[156] *Id.* § 1396w-4(h)(4).

[157] KAISER, *Medicaid Health Homes*, *supra* note 40, at 6.

[158] CMS, *Health Home Overview*, *supra* note 43, at 1; Moses & Klebonis, *supra* note 34, at 1.

[159] Moses & Klebonis, *supra* note 34, at 1.

[160] *Id.* at 2, 5.

[161] *See supra* notes 38, 76–79 and accompanying text.

[162] Moses & Klebonis, *supra* note 34, at 1.

[163] ASS'N OF STATE & TERRITORIAL HEALTH OFFICIALS & DEBEAUMONT FOUND., *supra* note 48, at 10.

[164] *See* Mohlman et al., *supra* note 112, at 9–10; Thomas A. Simpatico, *Vermont Responds to Its Opioid Crisis*, 80 PREVENTIVE MED. 10, 10 (2015).

of non-medical pain reliever use.[165] Among Vermont's Medicaid population, those suffering from opioid addiction had health care costs three times higher than the state's average Medicaid beneficiary, with only part of the cost differential attributable to the cost of opioid disorder treatment.[166] Apart from treatment costs, opioid dependent beneficiaries also had higher rates of "co-occurring mental health and other health issues" and use of "emergency rooms, pharmacy benefits, and other health care services."[167] Furthermore, use of illicit opioids was a primary contributor to Medicaid beneficiaries' drug overdoses.[168]

Amid the growing problems of opioid dependence and the demand for opioid treatment, the shortcomings of Vermont's existing MAT treatment system became evident.[169] In Vermont, like other states, the divergent federal regulation of buprenorphine and methadone, created a "bifurcated system of administering and providing . . . pharmacotherapy," leading to the development of several systemic treatment delivery problems.[170] While methadone programs "provided comprehensive addiction services," they failed to incorporate other mental and physical health services.[171] Similarly, buprenorphine prescribing providers offered inadequate access to addiction treatment and mental health services.[172] Ultimately, the existing system segregated methadone and buprenorphine prescribers and hindered communication between providers regarding patients they shared in common.[173] Therefore, in 2013, Vermont implemented a statewide health home model to address the inadequacies of its MAT delivery system.[174] Through the

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[165] VT. AGENCY OF HUMAN SERVS., INTEGRATED TREATMENT CONTINUUM FOR SUBSTANCE USE DEPENDENCE "HUB/SPOKE" INITIATIVE—PHASE 1: OPIATE DEPENDENCE 1 (Jan. 2012), http://atforum.com/documents/HUBSPOKEBriefingDocV122112.pdf [https://perma.cc/8SCL-JRFY].

[166] *Id.*

[167] *Id.*

[168] Anne VanDonsel et al., *Opioids in Vermont: Prevalence, Risk, and Impact*, VT. DEP'T OF HEALTH 38 (Oct. 27, 2016), http://www.healthvermont.gov/sites/default/files/documents/2016/12/ADAP_Opioids_Prevalence_Risk_Impact.pdf [https://perma.cc/PKT8-Z2ZD].

[169] *See* DEP'T OF VT. HEALTH ACCESS, VERMONT BLUEPRINT FOR HEALTH 2012 ANNUAL REPORT 44 (Feb. 15, 2013), http://www.leg.state.vt.us/reports/2013ExternalReports/287348.pdf [https://perma.cc/4SSG-7H89] ("Vermont's treatment programs had waiting lists, the number of physicians treating Vermonters for opioid dependence declined, and nearly 200 Vermonters traveled out of state to receive care.").

[170] ASS'N OF STATE & TERRITORIAL HEALTH OFFICIALS & DEBEAUMONT FOUND., *supra* note 48, at 12; *see also* DEP'T OF VT. HEALTH ACCESS, *supra* note 169, at 44.

[171] ASS'N OF STATE & TERRITORIAL HEALTH OFFICIALS & DEBEAUMONT FOUND., *supra* note 48, at 12; DEP'T OF VT. HEALTH ACCESS, *supra* note 169, at 45.

[172] ASS'N OF STATE & TERRITORIAL HEALTH OFFICIALS & DEBEAUMONT FOUND., *supra* note 48, at 12; DEP'T OF VT. HEALTH ACCESS, *supra* note 169, at 45.

[173] ASS'N OF STATE & TERRITORIAL HEALTH OFFICIALS & DEBEAUMONT FOUND., *supra* note 48, at 12–13; DEP'T OF VT. HEALTH ACCESS, *supra* note 169, at 45.

[174] DEP'T OF VT. HEALTH ACCESS, VERMONT BLUEPRINT FOR HEALTH 2013 ANNUAL REPORT 54 (Jan. 30, 2014),

health home model, the state sought to "[(1)] [i]ncrease access to MAT[,] [(2)] [s]trengthen the connection between specialty substance abuse treatment clinics and primary care . . . practices[,] [(3)] [e]nhance the services provided at methadone clinics and the . . . medical care at practices providing buprenorphine[,] [and (4)] [a]ssure financial stability."[175]

In devising its Hub and Spoke model, Vermont, known nationally as a health care innovator,[176] capitalized on its existing MAT infrastructure and its robust statewide health care delivery reform initiative, the Vermont Blueprint for Health (Blueprint).[177] Enacted in 2008, the Blueprint transformed the primary care system for Vermont Medicaid beneficiaries by creating an intricate network of PCMHs and community health teams (CHTs) to improve population health, "enhance[] the quality of care and patient experience," and reduce health care costs.[178] Consequently, the Hub and Spoke model was largely embedded into the provider relationships, primary care infrastructure, and payment reforms facilitated through implementation of the Blueprint.[179]

Under the Hub and Spoke, patients receiving MAT have an "established medical home, [either an OTP or buprenorphine prescribing practice], a single MAT prescriber, a pharmacy home, access to existing Blueprint [CHTs], and access to Hub or Spoke nurses and clinicians."[180] Depending on the complexity and severity of the patient's condition, patients are initially assigned to either a Hub or a Spoke, which is responsible for assessing the patient and devising an "integrated plan of care."[181]

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http://blueprintforhealth.vermont.gov/sites/blueprint/files/BlueprintPDF/AnnualReports/VTBlueprintforHealthAnnualReport2013.pdf [https://perma.cc/Q2VP-T2VB]; *see also supra* notes 169–173 and accompanying text.

[175] ASS'N OF STATE & TERRITORIAL HEALTH OFFICIALS & DEBEAUMONT FOUND., *supra* note 48, at 13; *see also* Casper & Folland, *supra* note 50, at 10 (footnote omitted).

[176] ASS'N OF STATE & TERRITORIAL HEALTH OFFICIALS & DEBEAUMONT FOUND., *supra* note 48, at 7; Simpatico, *supra* note 164, at 10 ("Vermont is one of the most forward-thinking states in the nation with a history of taking groundbreaking approaches to complex health and social issues.").

[177] Moses & Klebonis, *supra* note 34, at 5. See VT. STAT. ANN. tit. 18 §§ 702–707, 709 (West 2017), for discussion of Blueprint for Health initiatives.

[178] ASS'N OF STATE & TERRITORIAL HEALTH OFFICIALS & DEBEAUMONT FOUND., *supra* note 48, at 17 (citing DEP'T OF VT. HEALTH ACCESS, *supra* note 174, at 5); *see also* DEP'T OF VT. HEALTH ACCESS, *supra* note 169, at 2, 4–5; 46–47 (explaining Blueprint for Health initiatives). Because patients with complex health care needs often do not receive an adequate level of primary care services, CHTs are designed to "extend the capacity of primary care practices [by] assess[ing] patients' needs, coordinat[ing] community-based support services, and provid[ing] multidisciplinary care." DEP'T OF VT. HEALTH ACCESS, *supra* note 169, at 46; *see also* ASS'N OF STATE & TERRITORIAL HEALTH OFFICIALS & DEBEAUMONT FOUND., *supra* note 48, at 9. CHTs are "multi-disciplinary, community-based care coordination and support teams," ASS'N OF STATE & TERRITORIAL HEALTH OFFICIALS & DEBEAUMONT FOUND., *supra* note 48, at 9, "comprised of nurse coordinators, clinician case managers, social workers[,] and other professionals." DEP'T OF VT. HEALTH ACCESS, *supra* note 169, at 46.

[179] Casper & Folland, *supra* note 50, at 10–11; DEP'T OF VT. HEALTH ACCESS, *supra* note 169, at 46–47, 54–57.

[180] DEP'T OF VT. HEALTH ACCESS, *supra* note 169, at 47.

[181] Casper & Folland, *supra* note 50, at 11.

i. Hubs

Patients with complex addictions and comorbid health conditions are assigned to Hubs, regional OTPs equipped to provide methadone, buprenorphine, "support for ongoing care and prevention and treatment of relapse," and other services supporting the substance use disorder treatment plan.[182] In addition to providing treatment, Hubs must be capable of either directly providing or referring patients to a variety of other services, including social welfare, housing, and employment services.[183] Finally, Hubs are responsible for supporting Spokes through the provision of "induction and stabilization services for initiation of buprenorphine, reassessment and treatment recommendations if a patient relapses[,] . . . [and other] "recovery and rehabilitation services."[184]

ii. Spokes

In contrast to Hubs, Spokes provide buprenorphine in an outpatient setting and are designed to treat patients with less acute opioid dependence.[185] A Spoke consists of a buprenorphine prescribing physician and "collaborating health and addictions professionals who monitor adherence to treatment, coordinate access to recovery supports and community services, and provide counseling, contingency management, care coordination[,] and case management services."[186] Spoke practice settings are most commonly "primary care, ob-gyn, psychiatry, and practices specializing in the management of chronic pain."[187] Blueprint initiatives require Spokes to have one full-time nurse and one full-time licensed clinician case manager for every 100 MAT patients.[188]

Ideally, by integrating and coordinating delivery of care in Hubs and Spokes, "sufficiently stabilized" patients can transition from high intensity, high cost Hubs

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[182] *Id.* at 11–12; *see also* DEP'T OF VT. HEALTH ACCESS, *supra* note 169, at 47.

[183] ASS'N OF STATE & TERRITORIAL HEALTH OFFICIALS & DEBEAUMONT FOUND., *supra* note 48, at 19 (footnote omitted); Casper & Folland, *supra* note 50, at 12.

[184] ASS'N OF STATE & TERRITORIAL HEALTH OFFICIALS & DEBEAUMONT FOUND., *supra* note 48, at 19. Consultation services may include "psychiatry, addictions medicine, expertise in manag[ing] co-occurring mental health conditions, and recovery supports." Casper & Folland, *supra* note 50, at 12.

[185] Casper & Folland, *supra* note 50, at 11, 13; DEP'T OF VT. HEALTH ACCESS, *supra* note 169, at 47–48. Although a Spoke must have a credentialed physician, the following health care providers can serve as Spokes: "Blueprint Advanced Practice Medical Homes[,] [o]utpatient SUD treatment providers[,] [p]rimary care providers[,] Federally Qualified Health Centers[, and] [i]ndependent psychiatrists." CASPER & FOLLAND, *supra* note 50, at 13.

[186] DEP'T OF VT. HEALTH ACCESS, *supra* note 169, at 47.

[187] ANN VANDONSEL, VT. AGENCY OF HUMAN SERVS. DEP'T OF HEALTH, THE EFFECTIVENESS OF VERMONT'S SYSTEM OF OPIOID ADDICTION TREATMENT 6 (Jan. 15, 2015) (reporting to the Vermont Legislature), http://legislature.vermont.gov/assets/Legislative-Reports/Opioid-system-effectiveness-1.14.15.pdf [https://perma.cc/E85W-QN83].

[188] Casper & Folland, *supra* note 50, at 13. The Blueprint contracts with or hires Spoke staff, who function as part of the local CHT and then work directly in Spoke physician practices. *Id.* Because most Spokes prescribe to less than 100 patients, Spoke staff are often shared across multiple practices. *Id.*

to lower cost "office-based" Spokes.[189] Likewise, if a patient's condition worsens, the patient may be escalated from a Spoke to a Hub to ensure the patient continues receiving adequate treatment.[190]

D. The Beneficial Impact of the Hub and Spoke Model

Although Vermont is currently conducting a detailed evaluation of the impact of the Hub and Spoke model on "health care expenditures and utilization, clinical health outcomes, incarceration, and employment," [191] the Hub and Spoke has already produced several beneficial results.[192] The Hub and Spoke model has improved treatment capacity and access to care. Today, Vermont has five hubs with eight sites across the state, [193] which has tripled the number of patients receiving care in OTPs.[194] Though Spokes have seen less dramatic improvements in treatment capacity, since 2013, the total number of buprenorphine prescribing physicians has grown approximately 64%, and the number of unique Medicaid patients seen monthly has increased 38%.[195] The new delivery system also moderately increased the number of physicians actively treating ten or more Medicaid patients.[196] Overall, a growing number of Medicaid beneficiaries rely on the Hub and Spoke for MAT,[197] resulting in a 146% increase in the number of opioid dependent beneficiaries receiving treatment.[198]

In addition to improving treatment capacity, the Hub and Spoke model has facilitated the provision of more individualized and coordinated care for opioid dependent beneficiaries. Initially, to improve delivery of care and aid entities in implementing delivery system changes, Vermont's Medicaid program and the Vermont Department of Health Division of Alcohol and Drug Abuse Programs, devised standardized procedures and guidelines for the provision of MAT.[199] The Hub and Spoke model has also given physicians greater flexibility in making treatment decisions. For instance, unlike traditional federal OTPs, which provide

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[189] *Id.* at 18.

[190] *Id.*

[191] DEP'T OF VT. HEALTH ACCESS, VERMONT BLUEPRINT FOR HEALTH 2016 ANNUAL REPORT 53 (Dec. 29, 2016), http://blueprintforhealth.vermont.gov/sites/blueprint/files/BlueprintPDF/AnnualReports/Blueprint2016AnnualReport12.29.16.pdf [https://perma.cc/Z42Q-DG8A].

[192] *See infra* Section III.0.

[193] Casper & Folland, *supra* note 50, at 21.

[194] DEP'T OF VT. HEALTH ACCESS, *supra* note 191, at 50 ("The number of Vermonters in Hub programs . . . [went from] less than 1000 in 2013 to over 3,116 in October 2016.").

[195] DEP'T OF VT. HEALTH ACCESS, *supra* note 191, at 48.

[196] *Id.* at 48–49; *see* Harry Chen, *Status of Opioid Treatment Efforts*, VT. DEP'T OF HEALTH 17 (Oct. 25, 2016), http://www.leg.state.vt.us/jfo/healthcare/Health%20Reform%20Oversight%20Committee/2016_10_25/Status%20of%20Opioid%20Treatment%20Efforts%20-%20Chen.pdf [https://perma.cc/2AZ7-3DZC] (noting that as of October 2016, "45% of [S]poke prescribers prescribe[d] to more than 10 patients).

[197] Casper & Folland, *supra* note 50, at 22.

[198] Chen, *supra* note 196, at 16. The increased number of beneficiaries receiving treatment was largely due to increased caseloads in Hubs. VANDONSEL, *supra* note 187, at 9.

[199] VANDONSEL, *supra* note 187, at 19.

methadone almost exclusively, Hub physicians have the autonomy to determine whether a patient should initially be treated with buprenorphine or methadone.[200] The collaboration between Hubs and Spokes has also allowed approximately one-third of patients stabilized with buprenorphine in Hubs to continue treatment while transitioning to less intensive, less costly care in Spokes.[201] Throughout the course of the delivery system changes, 90-day treatment retention rates, which are crucial to treatment efficacy and the patient's long term functioning, have remained higher than the national average and continue to show an increasing trend.[202]

From a cost perspective, despite substantial investments in delivery system infrastructure and the imposition of higher medication costs through expanded use of buprenorphine, the Hub and Spoke model is expected to reduce overall health care expenditures.[203] A study conducted prior to complete implementation of the Hub and Spoke found that Medicaid beneficiaries receiving MAT with methadone or buprenorphine had lower overall annual health care expenditures than those receiving non-medication interventions.[204] This cost difference was partially explained by fewer inpatient admissions and outpatient hospital emergency department visits among MAT beneficiaries.[205] When compared to the average cost of a privately insured person with opioid use disorder, the average cost per person of a beneficiary participating in the Hub and Spoke system is approximately $46,954 less.[206] Ultimately, as of 2014, the Department of Vermont Health Access projected that "[d]ecreases in unnecessary and even higher-cost health care

[200] Casper & Folland, *supra* note 50, at 17 & n.11; *see supra* note 136–138 and accompanying text (highlighting the inefficiency of the limited prescription of buprenorphine in OTPs despite the fact OTPs are subject to less prescribing restrictions than physicians).

[201] Casper & Folland, *supra* note 50, at 18.

[202] VANDONSEL, *supra* note 187, at 15–16; VT. DEP'T OF HEALTH DIV. OF ALCOHOL & DRUG ABUSE PROGRAMS, VT. AGENCY OF HUMAN SERVS., ANNUAL REPORT ON VERMONT'S SUBSTANCE ABUSE SYSTEM OF CARE 23–24 (Jan. 13, 2016) (reporting to Vermont Legislature), http://legislature.vermont.gov/assets/Legislative-Reports/SA-annual-report-for-submission1.13.16.pdf [https://perma.cc/L2NS-PUEC]. Because of the enhanced intensity of care in Hubs, average retention rates in Hubs are 82.8%, compared to 69.3% in Spokes. VANDONSEL, *supra* note 187, at 15–16. As of 2014, retention rates had increased 4% since 2012. VT. DEP'T OF HEALTH DIV. OF ALCOHOL & DRUG ABUSE PROGRAMS, *supra*, at 23–24.

[203] Casper & Folland, *supra* note 50, at 16, 27.

[204] Mohlman et al., *supra* note 112, at 12–13. Average annual total medical expenditures among beneficiaries receiving MAT were $412 lower per beneficiary than expenditures in the non-MAT group. *Id.* at 12. When opioid addiction treatment costs were excluded, total expenditures were $2,409 lower for beneficiaries receiving MAT. *Id.* Beneficiaries in the MAT group also had "higher rates of pre- and perinatal care, [Hepatitis C virus] positivity, and more severe health status." *Id.; see also supra* notes 151–52 (providing further support for notion that medication costs may be offset by a reduction in other health care costs).

[205] Mohlman et al., *supra* note 112, at 12.

[206] Chen, *supra* note 196, at 22 (citing FAIR HEALTH, THE IMPACT OF THE OPIOID CRISIS ON THE HEALTHCARE SYSTEM 6 (Sept. 2016), https://www.fairhealth.org/publications/whitepapers (follow "Sep 2016: The Impact of the Opioid Crisis on the Healthcare System" hyperlink) [https://perma.cc/C7KQ-74NG]).

expenditures . . . [and] societal impacts and savings . . . in areas such as corrections, employment, . . . children in custody," and increases in productivity, would result in savings of $6.7 million.[207]

E. Limitations of the Hub and Spoke Model

Though the Hub and Spoke model appears to be a promising model for delivering MAT, Vermont has also experienced several challenges in its implementation and maintenance of the Hub and Spoke. Despite augmented treatment capacity and access under the Hub and Spoke model, the system remains inadequate to meet treatment demand.[208] This is evidenced by the fact that the increased caseload of patients receiving treatment has only marginally affected the widespread availability of heroin and the growing prevalence of heroin addiction.[209] Furthermore, regardless of Vermont's enhanced capacity to treat patients, many persons in need of treatment never seek care.[210] People most commonly cited affordability, lack of a desire to stop using opioids, lack of information regarding where to seek treatment, health insurance coverage issues, and transportation as reasons for not getting treatment.[211] Consequently, one's decision to forego treatment may be unrelated to a lack of access.

Although the transferability of patients in the current system marked a significant shift from the former system,[212] several limitations have plagued development of the ideal, synergistic relationship between Hubs and Spokes. Even with the baseline network of providers formed through the Blueprint initiative, establishing the processes, protocols, and relationships necessary to freely and efficiently transfer patients between Hubs and Spokes has been a substantial challenge.[213] While the Hub and Spoke dramatically increased patient caseload in Hubs, there was no parallel shift in the number of physicians prescribing buprenorphine[214] or the number of physicians actively treating more than ten patients.[215] Therefore, the shortage of medical providers in Spokes has restricted

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[207] Casper & Folland, *supra* note 50, at 27 (footnotes omitted).

[208] DEP'T OF VT. HEALTH ACCESS, *supra* note 191, at 47–48, 50–51; *see also id.* at 51 (noting that improvements in access to care largely varied by region); Casper & Folland, *supra* note 50, at 23; *id.* ("Continued waitlists . . . in the system show that the Hub and Spoke system is still facing unmet need.").

[209] VT. DEP'T OF HEALTH DIV. OF ALCOHOL & DRUG ABUSE PROGRAMS, *supra* note 202, at 7, 14.

[210] *Id.* at 19.

[211] *Id.*

[212] Casper & Folland, *supra* note 50, at 18.

[213] *Id.* at 18–19.

[214] VANDONSEL, *supra* note 187, at 9, 12.

[215] *See* DEP'T OF VT. HEALTH ACCESS, *supra* note 191, at 48–49; Chen, *supra* note 196, at 17 (indicating that most "spoke prescribers prescrib[ing] to more than [ten] patients" predominantly prescribe to "their own primary care patients with opioid use disorders").

care coordination, causing patients to remain in Hubs even when treatment in a Spoke is more appropriate.[216]

Vermont has actively attempted to encourage health care providers to offer MAT through trainings and other support,[217] but the following barriers persistently limit access and capacity to treat and coordinate care: "[(1)] patient complexity[,] [(2)] provider time[,] [(3)] lack of access to specialty care[,] [(4)] [physicians'] concern that [their] practice[s] will be flooded with too many addiction[] patients[, and] [(5)] skepticism about the efficacy of MAT."[218] In addition to workforce development challenges, federal regulations prohibiting sharing of substance use treatment information in the absence of the patient's consent have created another formidable obstacle to "effective integration of care and sharing of vital information."[219] Issues with information sharing are partially alleviated if a patient signs a standard release form containing the requisite elements,[220] but the release form still limits substance abuse providers' ability to access crucial information regarding the treatment or medications a patient received in a Hub.[221]

Thus, as Vermont continues to invest in its Hub and Spoke model and address the issues that have emerged thus far in implementation, it will be crucial to analyze whether the innovative health home model approach to delivering MAT improves health outcomes.

IV. THE EFFICACY OF VERMONT'S MEDICATION ASSISTED TREATMENT DELIVERY SYSTEM

Because of the unique demographic characteristics of Vermont's general and Medicaid populations, and its status as an innovative health care state, states considering whether to adopt a Medicaid health home parallel to Vermont's for the provision of MAT have reason to be skeptical. To address the opioid drug crisis, improve patient care, and reduce overall health expenditures, Vermont "combined a high cost structure with high cost medication."[222] In fact, from 2012 to 2016, Vermont's Medicaid spending on opioid treatment has nearly quadrupled;[223] and,

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[216] VT. DEP'T OF HEALTH DIV. OF ALCOHOL & DRUG ABUSE PROGRAMS, *supra* note 202, at 19–20; Chen, *supra* note 196, at 19.

[217] DEP'T OF VT. HEALTH ACCESS, *supra* note 191, at 51–52; Moses & Klebonis, *supra* note 34, at 5.

[218] DEP'T OF VT. HEALTH ACCESS, *supra* note 191, at 51.

[219] Moses & Klebonis, *supra* note 34, at 6; *see* 42 C.F.R. § 2.1 (2017); *see also* VT. DEP'T OF HEALTH DIV. OF ALCOHOL & DRUG ABUSE PROGRAMS, *supra* note 202, at 18–19.

[220] *See* 42 C.F.R. § 2.31 (2017).

[221] VT. DEP'T OF HEALTH DIV. OF ALCOHOL & DRUG ABUSE PROGRAMS, *supra* note 202, at 18–19 (noting that the data sharing requirements under 42 C.F.R. Part 2 are stricter than those HIPAA imposes).

[222] Casper & Folland, *supra* note 50, at 16.

[223] Chen, *supra* note 196, at 23.

amidst a large budget deficit, which some attribute to "[m]ushrooming Medicaid [c]osts,"[224] pressure on the Hub and Spoke model's success builds.[225]

But, in combination with the substantial increase in Medicaid spending, several of Vermont's distinguishing features may add further discomfort to states seeking an effective solution to the impending opioid drug crisis. Not only does Vermont have one of the highest rates of treatment capacity for opioid dependence,[226] it is also one of the smallest and least diverse states.[227] Compared to other states, Vermont spends more generously on its Medicaid population and therefore at baseline may be more willing to consider certain treatment options than other states. For instance, Vermont spends more per Medicaid enrollee than most states[228] despite having a Federal Medical Assistance Percentage (FMAP) of 53.47%, which indicates that Vermont has a higher per capita income than most states and is responsible for a greater portion of Medicaid costs.[229] In addition to demographic distinctions, Vermont implemented its Hub and Spoke model within the foundation of the Blueprint initiative,[230] which essentially made medical homes a central component of the state's Medicaid program. Not only did the Blueprint initiative provide a baseline network of providers across multiple agencies, it also facilitated the adoption of payment mechanisms rewarding the provision of quality, value based care rather than the traditional volume-based, fee-for-service form of reimbursement found in most states' Medicaid programs.[231]

Overall, Vermont's progressive approach should not discourage other states from considering innovative approaches, such as the health home model, to improve delivery of MAT to opioid dependent Medicaid beneficiaries. But, as states analyze the feasibility of implementing such a system, it is apparent that the challenges and resources necessary to create the proper infrastructure for the health home model could be more substantial in other states. The health home model dramatically alters traditional relationships among health care providers from both a payment and treatment perspective. Without a baseline initiative, such as

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[224] Nancy Remsen, *Mushrooming Medicaid Costs Create a State Budget Crisis,* VT.'S INDEP. VOICE: SEVEN DAYS (Jan. 13, 2016), http://www.sevendaysvt.com/vermont/mushrooming-medicaid-costs-create-a-state-budget-crisis/Content?oid=3111005 [https://perma.cc/2DYZ-MXP4].

[225] ASS'N OF STATE & TERRITORIAL HEALTH OFFICIALS & DEBEAUMONT FOUND., *supra* note 48, at 35.

[226] VanDonsel et al., *supra* note 168, at 6 (citing Jones et al., *supra* note 87, at e59–60).

[227] ASS'N OF STATE & TERRITORIAL HEALTH OFFICIALS & DEBEAUMONT FOUND., *supra* note 48, at 7.

[228] *See State Health Facts: Medicaid Spending Per Full-Benefit Enrollee*, KAISER FAMILY FOUND., https://www.kff.org/state-category/medicaid-chip/medicaid-spending-per-enrollee/ [https://perma.cc/E4J5-G2YC] (follow "Medicaid Spending Per Full-Benefit Employee" hyperlink) (last visited Nov. 18, 2017) (estimating spending per full-benefit employee as of fiscal year 2014).

[229] *State Health Facts: Federal Medical Assistance Percentage (FMAP) for Medicaid and Multiplier*, KAISER FAMILY FOUND., https://www.kff.org/state-category/medicaid-chip/medicaid-spending/ [https://perma.cc/B7DX-T65B] (follow "Federal Medical Assistance Percentage (FMAP) for Medicaid and Multiplier" hyperlink (last visited Nov. 18, 2017).

[230] *See supra* notes 176–179 and accompanying text.

[231] Casper & Folland, *supra* note 50, at 19; DEP'T OF VT. HEALTH ACCESS, *supra* note 191, at 11.

Blueprint, which transformed the organization of health care delivery in Vermont's Medicaid system, other states are at a significant disadvantage to attain the cost savings that may result from an improvement in health outcomes. Nonetheless, by eliminating the division between OTPs, buprenorphine prescribing physicians, and the overall health care system, and providing integrated care that addresses a patient's opioid dependence and other comorbid conditions, Vermont's Hub and Spoke model, and the health home model generally, offers states important insights into how MAT delivery can most effectively be modified to improve health outcomes.

CONCLUSION

Though the ACA was not originally designed with the opioid epidemic in view, its provisions, including Medicaid expansion, state health insurance exchanges, and the inclusion of addiction treatment as an essential health benefit, have provided insurance coverage to millions of Americans suffering from substance use disorders, including approximately one third with opioid use disorders.[232] Medicaid expansion alone is estimated to have provided drug treatment to approximately 1.3 million Americans.[233] Repeal of the ACA would eliminate such coverage of substance abuse treatment and "turn the clock back to a time when most Americans were subject to restrictive and inequitable limits on coverage" for MAT and other treatment services.[234] Consequently, "repeal and replace effort[s] [come] . . . at a critical time in the fight against opioid addiction."[235] Leaving Medicaid coverage of drug treatment and mental health services to state discretion means not only that fewer people would receive necessary treatment, but also that coverage of substance abuse treatment would be increasingly subject to state budgetary pressures.[236]

The opioid drug crisis "cuts across the lines of political polarization" and affects "nearly every community in this country."[237] Whether it is through the ACA or a different health plan, Medicaid coverage of opioid dependence prevention and treatment is crucial. As states brace for looming health policy changes, implementing a health home model for opioid dependent Medicaid beneficiaries remains a viable option for reforming the delivery of MAT. Undoubtedly, forming the infrastructure necessary to operate a health home is a significant undertaking. But, by building upon components of the existing treatment system and providing

[232] Friedmann et al., *supra* note 46, at e16(2).

[233] Dan Merica, *Trump's Plan for Medicaid Could Hurt the Opioid Abusers He Promised to Help*, CNN POL. (Mar. 12, 2017, 12:39 PM), http://www.cnn.com/2017/03/11/politics/donald-trump-medicaid-cuts-opioids/ [https://perma.cc/Y2N3-YDH8].

[234] Friedmann et al., *supra* note 46, at e16(2).

[235] Merica, *supra* note 233.

[236] *Id.*

[237] Friedmann et al., *supra* note 46, at e16(2).

more coordinated, effective care, it is possible that, in the long run, the health home model could help states reduce opioid-related morbidity and mortality and achieve overall cost savings.